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Occasional musings

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Is it irresponsible to publish procedural how-to's for rural doctors? Take the occasional epidural or caudal epidural steroid injection in this issue.^{1,2} Don't you need (insert the time the expert took to learn his or her entire specialty) years of training to be able to do it safely? Don't you need to perform (use a number here that doesn't exist in rural practice) procedures annually to keep up your skills? How can a mere rural general practitioner do this work?

And yet, take David Howe, author of the paper on caudal steroid injections, who practises in rural Nova Scotia. He was taught the technique on a model at an orthopedics course in Colorado, and he tells me that over the subsequent 20 years he has practised the technique perhaps monthly. It's not a huge series, but it is a large number of patients who have had meaningful reduction in pain. Don't try to tell me that they would have all gone to Halifax to see a specialist for similar results.

Another example is rural obstetrics, as detailed in the updated joint position paper on rural obstetric care, also in this issue.³ Rural obstetrics in this country is sustained by doctors who do occasional deliveries. Unless we are doing referral work, even those of us with large practices attend fewer than a dozen deliveries annually. There is evidence that, for obstetrics anyway, numbers do not matter, and that when patients with low-risk pregnancies have to travel for delivery, obstetric outcomes are actually worse.³

This does not necessarily mean that all procedures are for all doctors, rural or otherwise. It is my contention that you do need training and experience in broad-based general practice to perform

these procedures. Doctors particularly suited to rural medicine are intelligent people who have had 5 or 6 years of training supplemented by country experience that, among other things, informs them of the needs of their communities.

That country experience provides many opportunities for cross-training. For example, the technique I use to insert intrauterine contraceptive devices (which I learned in residency), is the same technique I taught myself to do hysterosalpingograms and endometrial biopsies. The discretion in patient selection I use for a patient with a stenotic cervix (who is best seen by a specialist) is the same discretion I use to decide which patients with acute myocardial infarction I keep and which I send to a specialist (we are too far from the bright lights of the city to divert patients for primary percutaneous transluminal coronary angioplasty). The same ultrasound findings that I look for in the rare abdominal trauma patient with internal bleeding, I see in my patients with ascites before I tap them. The echocardiograms I read in the emergency department help me to interpret tracings of patients undergoing a treadmill stress test.

No, publishing procedural how-to's is not irresponsible. If anything, not publishing them would be a disservice to the rural doctors who are our readership and, by extension, to the patients they care for in this country and others.

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1. Minty R, Kelly L. The occasional epidural steroid injection. *Can J Rural Med* 2012;17:148-50.
2. Howe D. Caudal epidural injection. *Can J Rural Med* 2012;17:145-7.
3. Joint Position Paper Working Group. Joint position paper on rural maternity care. *Can J Rural Med* 2012;17:135-41.

Réflexions sur les interventions occasionnelles

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Est-il irresponsable de publier des guides pratiques sur diverses interventions à l'intention des médecins en milieu rural ? Prenons par exemple les injections de stéroïdes par voie épidurale ou caudale dont est il question dans ce numéro^{1,2}. Ne faut-il pas (insérer ici le temps qu'il a fallu à un expert pour apprendre tout ce qui a trait à sa spécialité) années de formation pour être en mesure de les administrer en toute sécurité ? Ne faut-il pas effectuer (insérer ici un nombre qui ne correspond pas à la réalité de la pratique en milieu rural) procédures chaque année pour maintenir ses compétences ? Comment un simple omnipraticien rural peut-il faire ce travail ?

Et pourtant, prenons l'exemple du David Howe, médecin rural en Nouvelle-Écosse et auteur de l'article sur les injections de stéroïdes par voie caudale. Il a appris la technique sur un mannequin lors d'un cours d'orthopédie qu'il a suivi au Colorado. Il m'a confié qu'au cours des 20 années suivantes, il a pratiqué la technique presque tous les mois. Ce n'est pas un très grand nombre de procédures, mais cela représente tout de même un nombre important de patients qui ont ainsi connu une réduction significative de leur douleur. N'essayez pas de me dire qu'ils seraient tous allés voir un spécialiste à Halifax pour obtenir des résultats similaires.

Un autre exemple serait l'obstétrique en milieu rural, sujet décrit dans la mise à jour de l'énoncé de position commun sur les soins obstétricaux en milieu rural, que vous trouverez aussi dans ce numéro³. Au Canada, l'obstétrique en milieu rural est pratiquée par des médecins qui font des accouchements occasionnellement. À moins de recevoir des cas référés, même

ceux d'entre nous qui ont une pratique importante assistent à moins d'une douzaine d'accouchements par année. Tout indique que, pour l'obstétrique du moins, les chiffres n'ont pas d'importance, et que lorsque des patientes présentant des grossesses à faible risque doivent se déplacer pour accoucher, les résultats sont généralement pires³.

Cela ne signifie pas nécessairement que tous les médecins, ruraux ou autres, devraient pratiquer toutes les interventions. J'estime qu'il faut effectivement suivre une formation et acquérir de l'expérience dans une pratique générale pour apprendre à effectuer ces procédures. Les médecins particulièrement doués pour la médecine rurale sont des personnes intelligentes possédant 5 ou 6 années de formation auxquelles s'ajoute une expérience en milieu rural qui, entre autres choses, les informe sur les besoins des membres de leur collectivité.

Cette expérience en milieu rural offre de nombreuses occasions de formation polyvalente. Par exemple, la technique que j'utilise pour insérer un stérilet (que j'ai apprise en résidence) est la même que celle que j'ai apprise par moi-même pour faire des biopsies endométriales et des hystérosalpingographies. Le discernement dont je fais preuve dans la sélection des patientes présentant une sténose du col de l'utérus (qui devraient préférablement être prises en charge par un spécialiste) est le même que j'utilise pour décider, parmi les patients présentant un infarctus aigu du myocarde, lesquels je garde et lesquels je dirige vers un spécialiste (nous sommes trop loin des lumières de la ville pour y envoyer les patients subir une angioplastie coronaire transluminale percutanée). Les

mêmes résultats d'échographie que je recherche chez les rares patients ayant un traumatisme abdominal avec hémorragie interne, je les observe chez mes patients présentant une ascite, avant de faire une ponction. Les échocardiographies que j'ai examinées à l'urgence m'ont aidé à interpréter les tracés des patients subissant une épreuve d'effort cardio-respiratoire sur tapis roulant.

Non, il n'est pas irresponsable de publier des guides pratiques sur diverses interventions. En fait, c'est tout le contraire. Ne pas les publier rendrait un

mauvais service aux médecins des régions rurales qui sont nos lecteurs et, par extension, aux patients dont ils prennent soin ici et ailleurs dans le monde.

RÉFÉRENCES

1. Minty R, Kelly L. The occasional epidural steroid injection. *Can J Rural Med* 2012;17:148-50.
2. Howe D. Caudal epidural injection. *Can J Rural Med* 2012;17:145-7.
3. Joint Position Paper Working Group. Joint position paper on rural maternity care. *Can J Rural Med* 2012;17:135-41.

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CJRM seeks to promote research into rural health issues, promote the health of rural and remote communities, support and inform rural practitioners, provide a forum for debate and discussion of rural medicine, provide practical clinical information to rural practitioners and influence rural health policy by publishing articles that inform decision-makers.

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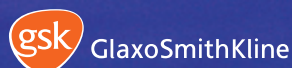
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The most commonly occurring side effects in COPD patients were upper respiratory tract infection (12-17%), throat irritation (8-11%), headache (16-18%), musculoskeletal pain (9-12%) and oral candidiasis (7-10%). In a 3 year study there was an increased reporting of any adverse event of pneumonia in patients receiving ADVAIR® DISKUS® when compared with placebo (16% vs. 9%).

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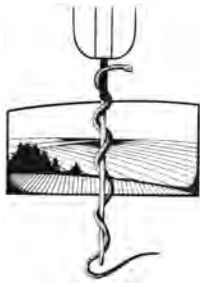


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In my previous president's message, I mentioned that the SRPC was deeply concerned that the mandatory 8-week rural rotation of family practice residents would be phased out or abolished by the new Triple C curriculum of the College of Family Physicians of Canada (CFPC) and the rewriting of the Red Book. "Triple C" stands for comprehensive, continuity of patient care and education, and centred in family medicine.¹

This sounds to me like a description of rural family medicine!

As this new curriculum is *competency-based* and not *time-based*, initial information reaching the ears of various SRPC members (who are also members of rural faculties across the country) raised concerns that the mandatory 8-week rural rotation of family practice residents would disappear. I attended a talk on the new curriculum in British Columbia and was not the only rural doctor who was worried, despite protestations by the speaker that rural physicians need not be concerned.

The SRPC wants everyone to be aware that the rural rotation remains a valuable opportunity for all residents to see medicine in the most comprehensive way possible. One of the benefits of the mandatory rural rotation has been the need for residents to use their skills to the fullest extent. The distinguishing feature about training in rural sites is the continuity of care; it is an opportunity to practise cradle-to-grave medicine, which is most easily learned in a rural setting. But it needs time — this cannot be taught over a weekend.

Through the rural rotation, residents gain exposure to the many facets of medicine. Some residents have been intimidated by the breadth of skills

required. Some have embraced its scope and enjoyed the opportunity to practise medicine in patients from conception to death. Others leave their rural site with the knowledge that rural family practice is not for them. For all these groups, a rural rotation is beneficial. Many of the skills learned in rural residency are directly transferable to other disciplines in medicine. The most obvious skill is learning to understand the patient as a human being and a member of the larger community. All of these outcomes are positive in terms of physician well-being and, ultimately, patient care.

For the SRPC, the bottom line is still that 9% of physicians are looking after 25% of the population. Will the new Triple C curriculum lead to more physicians in rural areas? In response to this concern, the SRPC has corresponded and had conversations with the CFPC and received quite reassuring replies. Nevertheless, the SRPC (through members on the forefront of academia and in rural areas — the undiscovered gems of medical training) continues to work on all fronts to ensure a beneficial outcome (for rural medicine AND rural Canadians).

The Latin saying in the title above is often followed by "*ubi loqui debuit ac potuit*," that is, "when he ought to have spoken and was able to." Thus, I urge you all to address this issue, if and where possible.

DO NOT HOLD YOUR PEACE!

REFERENCE

1. The College of Family Physicians of Canada. *Triple C competency-based curriculum: Canada's family medicine curriculum*. Available: www.cfpc.ca/triple_C/ (accessed 2012 Aug. 30).

*He who is silent is taken to agree. More liberally translated, speak now or forever hold your peace!

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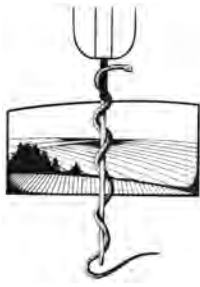
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Message du président. *Qui tacet consentire videtur**

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Dans mon précédent message du président, j'ai mentionné que la SMRC craint que le stage rural obligatoire de 8 semaines pour les résidents en médecine familiale ne soit graduellement supprimé ou aboli en vertu du nouveau *Cursus Triple C* axé sur les compétences du Collège des médecins de famille du Canada (CMFC) et par la révision approfondie du Livre rouge. Le *Cursus Triple C* « vise des soins complets et globaux, est orienté vers la continuité pédagogique et des soins aux patients [et] est centré sur la médecine familiale »¹.

Cela ressemble fort, à mon avis, à une description de la médecine familiale en milieu rural !

Étant donné que ce nouveau programme repose sur le *développement des compétences* et non sur un *horizon temporel*, les premiers échos qu'en ont entendus divers membres de la SMRC (qui appartiennent aussi à des facultés rurales un peu partout au pays) les ont incités à se demander si la rotation rurale obligatoire de 8 semaines pour les résidents en médecine familiale disparaîtrait. J'ai assisté à une conférence au sujet du nouveau programme en Colombie-Britannique et je n'étais pas le seul médecin rural préoccupé, malgré les protestations du présentateur qui affirmait que les médecins ruraux n'avaient pas à s'inquiéter.

La SMRC veut que tout le monde sache que le stage en milieu rural demeure une occasion précieuse pour tous les résidents de s'initier à la médecine de la façon la plus exhaustive possible. Le stage obligatoire en milieu rural oblige les résidents à utiliser tout l'éventail de leurs compétences. La caractéristique particulière de la forma-

tion en contexte rural, c'est la continuité des soins. Or, c'est en milieu rural qu'il est le plus facile d'en faire l'expérience, puisqu'on a l'occasion de soigner les patients du berceau au tombeau. Cet apprentissage prend toutefois du temps : ce n'est pas l'affaire d'un stage d'une fin de semaine.

Au cours d'un stage en milieu rural, les résidents sont exposés aux nombreuses facettes de la médecine. Certains résidents ont trouvé intimidant l'éventail des compétences requises. D'autres l'ont accueilli à bras ouverts et ont saisi l'occasion de pratiquer la médecine auprès des patients de la conception à la mort. D'autres encore terminent leur stage en sachant que la médecine familiale en milieu rural n'est pas pour eux. Pour tous ces groupes, un stage en milieu rural est bénéfique. De nombreuses compétences acquises au cours de la résidence rurale sont directement transférables à d'autres disciplines de la médecine. La compétence la plus évidente consiste à comprendre le patient comme un être humain et un membre de la collectivité. Tous les aspects du stage sont positifs pour le mieux-être du médecin et, en bout de ligne, pour le soin des patients.

Pour la SMRC, le nœud du problème, c'est toujours que 9 % des médecins s'occupent de 25 % de la population. Le nouveau *Cursus Triple C* aura-t-il pour effet de diriger davantage de médecins vers les régions rurales ? Face à cette préoccupation, la SMRC a écrit au CMFC avec lequel elle a aussi discuté de la question, et elle a reçu des réponses fort rassurantes. Néanmoins, la SMRC (par l'entremise de ses membres qui sont au premier plan dans les universités et en milieu rural — les

joyaux méconnus de la formation médicale) continue de travailler sur tous les fronts à assurer une issue positive (pour la médecine rurale ET pour les Canadiens des régions rurales).

La maxime latine citée dans le titre ci-dessus est souvent suivie de la phrase « *ubi loqui debuit ac potuit* », ce qui signifie « quand il aurait dû et pu prendre la parole ». Ainsi, je vous exhorte tous et toutes à vous prononcer au sujet de cette question, partout et à chaque fois qu'il vous sera possible de le faire.

NE GARDEZ PAS LE SILENCE !

RÉFÉRENCE

1. Le Collège des médecins de famille du Canada. *Le Coursus Triple C axé sur les compétences : le cursus en médecine familiale au Canada*. Disponible ici : www.cfpc.ca/ProjectAssets/Templates/Category.aspx?id=4333&langType=3084 (consulté le 30 août 2012).

*Qui se tait semble consentir. On pourrait aussi dire : parlez maintenant ou gardez le silence à jamais !

DIRECTIVES AUX AUTEURS

Le *Journal canadien de la médecine rurale (JCMR)* est un trimestriel critiqué par les pairs disponible sur papier et sur Internet. Le *JCMR* est le premier journal de médecine rurale au monde à être inscrit dans Index Medicus et dans les bases de données MEDLINE et PubMed.

Le *JCMR* vise à promouvoir la recherche sur les questions de santé rurale, à promouvoir la santé des communautés rurales et éloignées, à appuyer et informer les praticiens en milieu rural, à offrir une tribune de débat et de discussion sur la médecine rurale, ainsi qu'à fournir de l'information clinique pratique aux praticiens en milieu rural et à agir sur la politique de santé rurale en publiant des articles qui éclairent les décideurs.

On étudiera la possibilité de publier des documents dans les catégories suivantes.

Articles originaux : études de recherche, rapports de cas et analyses critiques d'écrits en médecine rurale (3500 mots ou moins)

Commentaires : éditoriaux, analyses régionales et articles d'opinion (1500 mots ou moins)

Articles cliniques : articles pratiques pertinents pour la pratique en milieu rural. On encourage la présentation d'illustrations et de photos (2000 mots ou moins)

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Couverture : œuvre d'art à thème rural

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Envoyer deux copies papier du manuscrit au Rédacteur en chef, *Journal canadien de la médecine rurale*, 45, boul. Overlea, C. P. 22015, Toronto ON M4G 3Z3, ainsi qu'une version électronique, de préférence par courriel à cjrm@cjrm.net, ou sur CD. Veuillez préparer la version électronique dans le format Word 2003 ou antérieur, soit le format doc, et non le format docx). Il faut joindre les illustrations et les photos numériques dans des fichiers distincts (voir ci-dessous).

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Epidural steroid injections for low back pain in rural practice: a 5-year retrospective study

See related articles on pages 119, 145 and 148.

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This article has been peer
reviewed.

Introduction: Epidural steroid injections (ESIs) are a safe and accessible therapy for chronic low back pain, one of the most common and challenging chronic conditions seen in primary care. However, the indications for and effectiveness of ESI remain controversial. In rural settings with limited public transportation infrastructure, such a mobility-limiting condition can have even more negative effects on quality of life and function. Furthermore, diagnostic and specialist services are often limited. A paucity of safe, effective and accessible treatments leads to heavy reliance on oral analgesics, especially opioids, which have well-known complications.

Methods: We reviewed the use of ESI for the 2 most common types of chronic low back pain in those with neurologic symptoms: lumbar disc herniation (LDH) and lumbar spinal stenosis (LSS). We did a retrospective chart review of all patients who underwent ESI between Jan. 1, 2005, and Feb. 25, 2010, at our rural hospital in northwestern Ontario.

Results: During the study period, 123 ESIs were administered to 65 patients. After the first injection, 40 patients (62%) reported improvement, 10 (15%) reported worsening or no change, and 15 (23%) had no follow-up documented.

Conclusion: Some patients with neurologic compromise from LDH or LSS have improvement in symptoms after ESI. A prospective study is underway to more rigorously assess the effectiveness of this treatment.

Introduction : Les injections épidurales de corticostéroïdes (IEC) constituent un traitement sécuritaire et accessible de la lombalgie chronique, une des affections chroniques les plus courantes et complexes en médecine de premier recours. Les indications et l'efficacité des IEC ne font cependant pas consensus. En milieu rural, où les infrastructures de transport public sont limitées, une maladie qui affecte autant la mobilité peut avoir des effets encore plus négatifs sur la qualité de vie et le fonctionnement. En outre, les services diagnostiques spécialisés sont souvent restreints dans ces régions. Le manque de traitements sécuritaires, efficaces et accessibles entraîne une importante dépendance aux analgésiques oraux, particulièrement aux opiacés, dont les complications sont bien connues.

Méthodes : Nous avons passé en revue l'utilisation des IEC pour les 2 plus courants types de lombalgie chez des sujets qui en présentent des signes neurologiques : la hernie discale lombaire (HDL) et la sténose spinale lombaire (SSL). Nous avons examiné de manière rétrospective les dossiers de tous les patients qui ont reçu des IEC entre le 1^{er} janvier 2005 et le 25 février 2010 dans notre hôpital rural du Nord-Ouest de l'Ontario.

Résultats : Durant la période de l'étude, 123 IEC ont été administrées à 65 patients. Après la première injection, 40 patients (62 %) ont signalé une amélioration de leur état, l'état de 10 patients (15 %) s'est aggravé ou est resté stationnaire et pour 15 sujets (23 %), nous n'avons pas obtenu de données de suivi.

Conclusion : Certains patients qui éprouvent des difficultés neurologiques en raison d'une HDL ou d'une SSL voient leurs symptômes s'améliorer après des IEC. Une étude prospective est en cours pour évaluer plus rigoureusement l'efficacité de ce traitement.

INTRODUCTION

Low back pain is among the most common presenting symptoms in primary care.^{1,2} Whereas the vast majority of patients presenting with back pain have an excellent prognosis for both pain relief and functional recovery, the smaller number of chronic cases that require prolonged follow-up constitute a disproportionate number of clinic visits. In a rural setting, these patients typically travel long distances for advanced imaging and orthopedic referral.

Detailed pathophysiologic models and classification systems are in stark contrast to the great uncertainty faced by primary care clinicians and specialists in specific cases: an estimated 85% of cases cannot be given a precise diagnosis.^{3,4} The uncertainties arise from both the complexity of the disease entity itself, and from the limitations of our tools and models.

Chronic back pain often interacts with a host of other medical and psychological impairments, with each condition exacerbating the others and complicating management. In one survey, 20% of patients with lumbar spinal stenosis (LSS) reported symptoms of depression and 25% reported being "generally dissatisfied with life."^{5,6}

Frequently used terms such as "sprain," "strain," and "degeneration" have no widely accepted histologic or anatomic definition and are effectively synonymous with "idiopathic."⁷ The association between clinical and imaging findings on the one hand and patient distress and disability on the other is generally poor. Physical findings, although clear-cut in many acute cases, become increasingly ambiguous in more chronic ones. Inappropriate use of imaging is widespread and well-documented.⁸⁻¹⁰ The functional relevance of "abnormal" findings is often unclear. Potentially significant findings such as bulging or herniated discs turn out to be very common, even among asymptomatic adults,¹¹⁻¹⁴ and are often incidental, even in symptomatic patients. Such findings can lead to overdiagnosis, increased anxiety, and unnecessary and potentially harmful treatments.⁷ These uncertainties manifest as wide variations in diagnostic workup and treatment.⁴

At initial presentation, the first concern is ruling

out rare (1%–3%)⁷ but potentially life- and limb-threatening causes of back and lower extremity pain: cauda equina syndrome, tumour, epidural abscess, spinal osteomyelitis and aortic aneurysm.¹⁵ Fortunately, although these conditions do have their own diagnostic challenges, the key to accurate diagnosis remains an index of suspicion and thorough evaluation, which may involve emergency, long-distance transport for rural patients.

Of the remaining, so-called mechanical, cases, about 70% are short-lived, often labelled as "sprain" or "strain," and another 10% are due to nonspecific degenerative changes in discs and facet joints.⁷ Lumbar spinal stenosis and lumbar disc herniation (LDH) each account for 3%–4% of cases at initial presentation,¹⁵ but can portend a more chronic course and hence constitute a much larger portion of prevalent disease. Whereas 90% of patients presenting with nonspecific back pain within 3 days of onset recover within 2 weeks,¹⁶ those patients with LSS are likely to experience persistent or worsening pain, despite little progression in neurologic dysfunction. Two follow-up LSS studies (which included 32 and 47 patients, respectively) suggested that 50%–75% of patients with this diagnosis experience either persistent or worsening symptoms.^{17,18} In distinction, LDH has a more favourable natural history, with most patients showing significant clinical improvement within the first 6 weeks.¹⁹ A magnetic resonance imaging follow-up study has suggested that the herniation itself resolves at least partially in two-thirds of cases.²⁰

As with other conditions of subacute and chronic pain, there has been little progress in developing safe, accessible and reliably effective therapies. In a rural setting with limited public transportation infrastructure and large distances, the mobility limitations imposed by back pain can have even greater consequences for quality of life and function. In addition, diagnostic and therapeutic facilities are less accessible in such areas. Frequently, opioid analgesics become the only option for symptomatic treatment, with their limited effectiveness and long-term medical and social complications.²¹

Epidural steroid injections (ESIs) represent a fairly economical, accessible and safe alternative in

In general, the effectiveness of surgery for chronic back pain remains controversial, and there is no consensus on specific indications. The general trend in outcomes is a transient improvement in pain scores in the first 1–5 years, with perhaps subtle improvement in disability and functional outcomes in the first 1–2 years. The longest follow-up data on LSS comes from the Maine Lumbar Spine Study,^{39–41} which followed a cohort of 148 patients for 10 years. Patients who received surgical treatment had more severe symptoms and worse functional status at baseline, and better outcomes at 4-year evaluation than the patients who received nonsurgical treatment.

Epidural steroid injections

Epidural steroid injections are a safe and widely available alternative treatment. Three techniques are commonly used: interlaminar (“classic”), transforaminal and caudal. The transforaminal approach requires fluoroscopic guidance, which is not commonly available in many rural centres. Both the caudal and transforaminal techniques require specific skills, whereas most rural anesthesia providers are proficient at interlaminar epidural injections, commonly used in obstetrics.

Overall, the evidence regarding the effectiveness of ESI over placebo is vast, yet inconclusive. The latest Cochrane review on the subject found a lack of evidence, not only for epidural steroids but also for other injection therapies for subacute or chronic low back pain.⁴² Some studies have reported a range of benefits, from reducing symptoms to delaying or reducing the rates of surgery,^{43–45} whereas others have found no benefit.⁴⁶ Difficulties in diagnosing the exact cause of chronic low back pain make classification of patients and identification of clinically relevant subgroups difficult. It may be that certain etiologies of low back pain are more responsive to epidural steroids than others. In addition, comparison of the techniques used in the positive versus negative trials suggests that the choice of steroid may be important, with nearly all studies using methylprednisolone having negative findings and most studies using other steroids finding some benefit.⁴⁵ Thus far, our centre has been using only methylprednisolone for ESIs.

METHODS

Data collection and analysis

Charts for all patients who underwent an ESI between Jan. 1, 2005, and Feb. 25, 2010, were

reviewed by one of the authors (L.M.). Demographic data, presenting symptoms, diagnosis, imaging results, comorbidities, dates and number of ESIs were coded. The patients had been referred by their family physicians to 2 local general practitioner–anesthetists. We were primarily interested in patients’ diagnosis at the time of injection and their response to treatment.

Outcome at follow-up was documented as “improved,” “no difference/worse” or “no follow-up,” as recorded in the chart. This represented physicians’ overall impression based on the patient’s reports of symptom severity, as well as physical findings. There was substantial variation in the type and detail of follow-up data available, as this was a retrospective chart review.

Data were collected in Excel and imported into IBM SPSS software (version 19.0 for Windows). Data were initially analyzed descriptively, with frequencies and percentages for categorical data and means and standard deviations for continuous data. The characteristics of those who saw improvement, saw no improvement or were lost to follow-up after the initial injection were compared using Pearson χ^2 tests for categorical data, and one-way analysis of variance for continuous data.

Research ethics approval was obtained from the Sioux Lookout Meno Ya Win Research Review Committee.

Method of injection

Before the injection, the physician discussed the risks and procedure with each patient. All patients sat in lumbar flexion on an operating table. The iliac crest was used as a reference point for the L3–4 interspace. From there, the level of injection was identified based on imaging results and patient anatomy. Using sterile technique, after subcutaneous lidocaine injection, the epidural space was identified using loss-of-resistance to air with a 17-gauge Tuohy needle, and 80 mg of methylprednisolone in 5 mL of 0.9% saline was injected. All patients received advice on postinjection management and instructions to follow up with their family physicians.

Previous back surgery, such as spinal fusion, laminectomy or discectomy, often alters access to the epidural space. As a result, in some cases the injection was given 1 level above or below the affected site.

RESULTS

During the 5-year study period, 123 ESIs were administered to 65 patients. Characteristics of the

the rural setting. Their effectiveness, however, has been controversial since their introduction in 1953.²² Most ESI research to date focuses on LDH, often excluding patients with LSS.

In this paper, we briefly review the literature on ESI for low back pain related to LSS and LDH, and present 5 years of clinical experience in a rural hospital. We have included both LDH and LSS patients in our study. To our knowledge, this is the first study to be undertaken in a rural setting using general practitioner–anesthetists undertaking classic epidural technique without advanced imaging. This is currently the only widely available delivery model for ESI in the rural setting.

LOW BACK PAIN, LDH AND LSS

Lumbar disc herniation results from degenerative tears in the annulus fibrosus of the intervertebral discs, leading to herniation of nucleus pulposus into the spinal canal, or neural foramina.²³

Lumbar spinal stenosis is the gradual narrowing of the spinal canal, or the lateral recesses and neural foramina, leading to radicular or chordal neurologic dysfunction. It can arise congenitally²⁴ (primary disease) or, far more commonly, secondary to hypertrophic degenerative changes, degenerative disc disease or less common conditions.²⁵ The most frequent sites of clinically significant stenosis are the lumbar followed by the cervical spine.

In both cases, the resulting mechanical stress and tissue injury can trigger a complex of still poorly understood neurologic, inflammatory, microcirculatory, immune and endocrine changes. Compression can lead to local inflammation; sensitization of surrounding tissue and changes in the excitatory state of nerves;²⁶ impairment of arterial supply and venous return, leading to ischemia and further inflammation;^{27,28} autonomic dysregulation and further impairment of circulation;²⁷ and exacerbation of pain.

The classic manifestation of LSS is neurogenic claudication: a constellation of uni- or bilateral weakness, dull pain and fatigue involving the legs and lower back, worsening with activity and backward extension (e.g., walking downhill, looking up) and improving with rest and forward flexion (e.g., walking uphill, pushing a cart).²⁹ It is typically accompanied by sensory abnormalities, such as numbness and paresthesia.⁷ Consistent with a slow degenerative etiology, patients usually present with a history of months to years of gradually increasing symptoms.

Unlike most cases of LSS, the source of mechanical stress in LDH tends to arise more suddenly and

regress in most cases.^{19,20} However, despite differences in initial etiology, chronic cases of LDH likely involve the same pathophysiologic processes as LSS, with stenosis being caused by the herniated disc and the associated inflammatory and degenerative changes.

MANAGEMENT

Nonsurgical treatment

In addition to treatment for medical and psychiatric comorbidities, conservative management for low back pain consists of activity modification (to reduce spinal extension), conditioning exercise, stretching, physiotherapy, meditation and relaxation techniques, and transcutaneous electrical nerve stimulation.³⁰ Trials of conservative management regimens typically use multimodal strategies and report some improvement in up to 70% of cases.^{31–33}

Oral analgesics, usually nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids, are used frequently but with limited effectiveness. There is no clear evidence for the benefit of one class over another, and both have potentially substantial side effects with prolonged use. NSAIDs are associated with renal impairment and gastrointestinal bleeding and, in the case of cyclooxygenase-2 inhibitors, potentially elevated cardiovascular risk.³⁴ The high incidence of diabetes and diabetic renal compromise in many rural populations, such as in our own catchment area in northern Ontario, limits the use of NSAIDs. Opioids, on the other hand, are associated with tolerance, potential abuse and dose-related risk of death.²¹ One recent study suggests that the use and dose of opioids for nonmalignant pain in socioeconomically disadvantaged patients has substantially increased in the province of Ontario,²¹ leading to increased mortality.

Surgery

For LDH without symptoms of cauda equina syndrome or foot drop, conservative management is recommended for at least 1 month, as only 10% of patients have sufficient pain after 6 weeks to consider surgery.⁷ Lumbar discectomy is the most common surgical treatment for refractory pain from LDH and has been documented to offer improved pain relief for up to 4 years.⁷

Lumbar spinal stenosis has a much higher rate of surgical intervention and has become the most frequent indication for spinal surgery in adults older than 65 years.^{35–37} Lumbar laminectomy for LSS is better supported by outcome evidence than the more complex instrumented fusion procedures.^{35,38}

patients are provided in Table 1. Given the small sample and our aim of identifying factors for future investigation, we highlight all findings with $p < 0.15$. Slightly more than half of all patients were female, one-third self-identified as Aboriginal and the aver-

age age at first injection was 55 years.

The most common comorbidities were hypertension (52%), osteoarthritis (49%), psychosocial conditions (37%) and type 2 diabetes (32%). The most commonly documented initial symptoms were back

Table 1. Characteristics of patients, by outcome after first epidural steroid injection

Characteristic	No. (%) of patients*†				p value‡
	Total, n = 65	No improvement, n = 10	Improvement, n = 40	Lost to follow-up, n = 15	
Age, yr, mean (SD)	54.8 (18.5)	48.6 (20.9)	56.2 (17.4)	55.1 (19.9)	0.51
Sex					0.70
Male	27 (42)	3 (11)	17 (63)	7 (26)	
Female	38 (58)	7 (18)	23 (61)	8 (21)	
Aboriginal (self-identified)	24 (37)	4 (17)	16 (67)	4 (17)	0.64
Location					0.26
Sioux Lookout, Ont.	42 (65)	5 (12)	24 (57)	13 (31)	
Northern community	15 (23)	4 (27)	10 (67)	1 (7)	
Other/unknown	8 (12)	1 (13)	6 (75)	1 (13)	
Radiographic diagnosis					
Lumbar spinal stenosis	33 (51)	4 (12)	22 (67)	7 (21)	0.65
Lumbar disc herniation	52 (80)	9 (17)	30 (58)	13 (25)	0.44
Spondylolisthesis	16 (25)	3 (19)	10 (63)	3 (19)	0.85
Back pain NYD	5 (8)	1 (20)	2 (40)	2 (40)	0.58
Symptoms					
Leg pain	54 (83)	8 (15)	35 (65)	11 (20)	0.44
Leg weakness	31 (48)	8 (26)	17 (55)	6 (19)	0.08
Leg numbness	33 (51)	8 (24)	19 (58)	6 (18)	0.11
Positive "shopping cart" test	8 (12)	2 (25)	6 (75)	0 (0)	0.23
Bowel or bladder incontinence§	9 (14)	3 (33)	4 (44)	2 (22)	0.26
Limited exercise tolerance	36 (55)	6 (17)	22 (61)	8 (22)	0.95
Abnormal deep tendon reflexes	25 (39)	5 (20)	15 (60)	5 (20)	0.60
Back surgery	15 (23)	4 (27)	9 (60)	2 (13)	0.29
Analgesic use					
Narcotics	37 (57)	7 (19)	23 (62)	7 (19)	0.51
NSAIDs	42 (65)	5 (12)	26 (62)	11 (26)	0.49
Other analgesics	28 (43)	4 (14)	17 (61)	7 (25)	0.94
Physiotherapy					0.37
No physiotherapy	31 (48)	3 (10)	21 (68)	7 (23)	
Education/exercise	16 (25)	2 (13)	10 (63)	4 (25)	
Physiotherapy	16 (25)	5 (31)	7 (44)	4 (25)	
Comorbidities					
Type 2 diabetes	21 (32)	2 (10)	15 (71)	4 (19)	0.49
Osteoarthritis	32 (49)	4 (13)	20 (63)	8 (25)	0.78
Rheumatoid arthritis	3 (5)	1 (33)	1 (33)	1 (33)	0.51
Peripheral vascular disease	6 (9)	0 (0)	5 (83)	1 (17)	0.46
Psychosocial (anxiety, depression, stress)	24 (37)	5 (21)	13 (54)	6 (25)	0.61
Hypertension	34 (52)	3 (9)	25 (74)	6 (18)	0.08
Coronary artery disease	12 (19)	1 (8)	7 (58)	4 (33)	0.57
Cerebrovascular disease	6 (9)	0 (0)	3 (50)	3 (50)	0.21
Scoliosis	11 (17)	2 (18)	5 (46)	4 (37)	0.52

Note: Findings with p values < 0.15 are highlighted in bold.

NSAID = nonsteroidal anti-inflammatory drug; NYD = not yet diagnosed; SD = standard deviation.

*Unless stated otherwise.

†For the full sample, percentages are out of 65; for the 3 outcome groups, percentages are by row. Percentages do not always total 100 because of rounding.

‡Tests of significance are based on the t test (age) and the χ^2 test (all others, Pearson or Fisher Exact test as appropriate).

§All cases of bowel and bladder incontinence were chronic. None of the patients in this series presented with cauda equina syndrome.

pain (all), leg pain (83%), limited exercise tolerance (55%), leg numbness (51%) and leg weakness (48%). Sixty-one of the patients had computed tomography or magnetic resonance imaging; of these, 80% had disc herniation or bulging in at least 1 level, 51% had LSS and 25% spondylolisthesis. Only 1 patient had no abnormalities on imaging. There were no cases of acute cauda equina syndrome in the group.

Outcomes of ESI

Of the 65 patients who received a first injection, 33

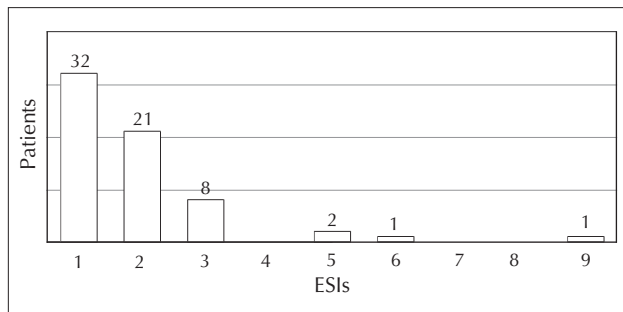


Fig. 1. Number of epidural steroid injections (ESIs) per patient (total 123 ESIs in 65 patients).

(50%) had subsequent injections, with 12 (18%) having 3 or more (Fig. 1). The interval between injections ranged from 9 days to 4 years, with a median of 109 days (Fig. 2).

After the first injection, 40 (62%) reported improvement, 10 (15%) reported worsening or no change and 15 (23%) had no follow-up documented. Of the patients who had multiple injections, 58%–67% reported improvement. The outcome data for the 123 ESIs are presented in Figure 3. Patients whose symptoms improved with their first ESI were somewhat more likely to receive future injections ($p = 0.17$).

Comparison of groups

Factors associated with improvement ($n = 40$), no improvement ($n = 10$), or loss to follow-up ($n = 15$) are presented in Table 1. Those with no improvement tended to be somewhat younger than those who did improve or were lost to follow-up (49 years of age compared with 56 and 55 years, respectively), but this association was not significant ($p = 0.51$).

Two symptoms showed a potentially significant

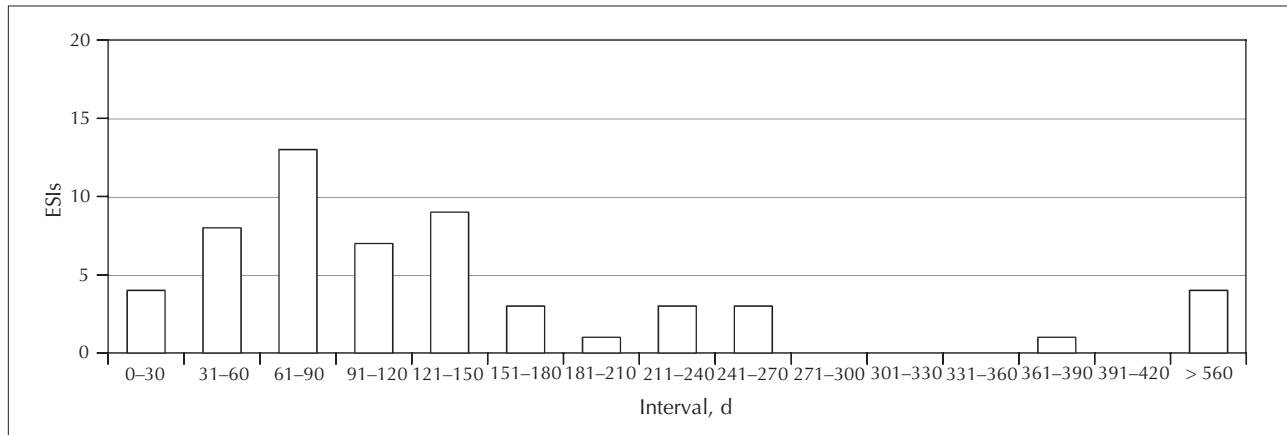


Fig. 2. Interval between procedures in patients who had more than 1 epidural steroid injection (ESI; 59 ESIs in 33 patients).

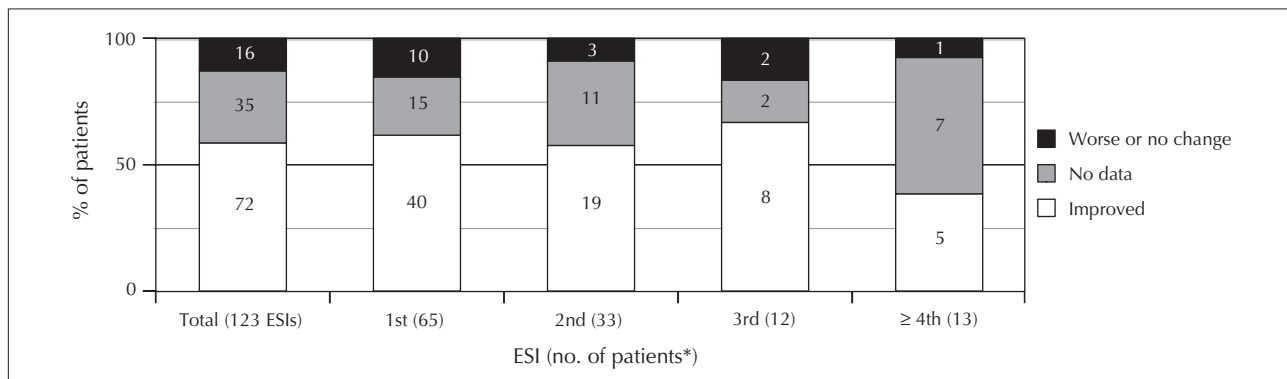


Fig. 3. Outcome in epidural steroid injections (ESIs), by total ESIs performed and by number performed in patients. *Unless stated otherwise.

association with a negative outcome: leg weakness ($\rho = 0.08$) and leg numbness ($\rho = 0.11$). Both are suggestive of neurologic dysfunction. Hypertension was the only comorbidity potentially associated with injection outcome ($\rho = 0.08$), with the improved group having a higher proportion of patients with hypertension. More than half of those whose symptoms improved did so despite having no access to physiotherapy. There were no apparent associations between diagnosis and ESI outcome, or between analgesic use and ESI outcome. More patients with LSS had improved symptoms than those with LDH, although many patients had both LSS and LDH (Table 1).

Surgery

Fifteen of 65 patients had documented back surgery. Six patients had undergone back surgery before the study period and 10 had surgery during the study period (1 patient had both). Three patients underwent 2 surgeries. The type of surgery was not documented for 2 of the 15 patients. Of the remaining 13 patients, 2 underwent spinal fusion, and 11 had 1 or 2 laminectomy/discectomy procedures.

One patient had undergone 2 previous surgeries and received 9 ESIs during the period under review. Excluding this patient, the number of injections for patients who underwent surgery (either before or after) ranged from 1 to 6 with an average of 1.8, similar to the overall average.

DISCUSSION

Inferences from these data regarding the effectiveness of ESI are limited by the retrospective nature of the study, the incompleteness and potential inconsistency of follow-up data, and the real-world complexities of copathology and diagnostic uncertainty.

Although the sample is small, and therefore underpowered, the data do suggest that symptoms of leg weakness and numbness may be associated with poorer outcomes. Among those with follow-up data, 80% had documented improvement. We cannot say whether this is an improvement over the natural history of the disease.

Epidural steroid injections can be a useful therapy for a common and symptomatic condition, in settings where other options are limited. Whereas fluoroscopically guided techniques are a common standard in the literature, our study highlights that commonly used obstetric anesthesia techniques available in many rural areas can provide positive results. As such, the pre-

cise indications and effectiveness of epidural steroids in rural areas deserves more rigorous study.

CONCLUSION

We have documented that some patients with neurologic compromise, from either LSS or LDH, seem to have improvement of symptoms after an ESI, but the retrospective nature of our study does not allow us to draw any clear causal links. This requires larger, prospective pools of clinical data, as well as improved understanding of the pathophysiologic mechanisms of chronic back pain and the potential points of therapeutic intervention. We have already begun a multicentred prospective rural study of the effectiveness of ESIs.

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JOINT POSITION PAPER DÉCLARATION DE PRINCIPLE COMMUNE

Joint position paper on rural maternity care

Sommaire en français à la page 142

This joint position paper has been prepared by the Joint Position Paper Working Group and approved by the Canadian Association of Midwives, the Canadian Association of Perinatal and Women's Health Nurses, the College of Family Physicians of Canada, the Society of Obstetricians and Gynaecologists of Canada and the Society of Rural Physicians of Canada.

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A review of the current literature on issues of maternity care relevant to rural populations underpins 14 recommendations prepared and approved by 5 national physician, midwifery and nursing organizations. This review and these recommendations are intended to help rural obstetric care providers to continue to provide quality care for women in their communities.

INTRODUCTION AND BACKGROUND

Canadian women deserve quality maternity care regardless of whether they live in urban, rural or remote communities. Individual health care providers must work to develop and maintain models of maternity care adapted to the communities in which women reside and to the resources available. Building on the 1998 Joint Position Paper on Rural Maternity Care,¹ this enhanced document includes new evidence. Acknowledging that interprofessional care of women through the continuum of prenatal, intrapartum and postnatal periods is the norm, this paper represents the collaboration among not only physician organizations, but also nursing and midwifery organizations. The authors of this paper and their respective organizations have agreed that rural maternity care must include agreement on the following overarching recommendations.

Recommendations 1 to 3

1. Women who reside in rural and remote communities in Canada should receive high-quality maternity care

as close to home as possible.

2. The provision of rural maternity care must be collaborative, woman- and family-centred, culturally sensitive and respectful.
3. Rural maternity care services should be supported through active policies aligned with these recommendations.

Defining “rural” in Canada remains challenging. Rurality indices attempt to capture the essence of rural with variables such as the distance between the site and advanced care, between the site and basic care, as well as the population number and density of the site.² This definition attempts to cover the variety of rural centres from those that are geographically isolated to centres that, while close to basic and advanced care, are in regions with low population density. Rural maternity care is often characterized by maternity care teams led by family physicians, nurses and midwives. In some communities, they are the only ones providing maternity care, and in other cases backup is provided by general surgeons, general practitioner (GP)–anesthetists, obstetrician-gynecologists and/or family physicians with surgical training.

Recent years have seen the closure of rural maternity programs as part of

regionalization of care and cost-cutting.⁵ In addition to administrative pressures, lack of skilled personnel in maternity care has resulted in service decreases and program closures.⁴ Maternity programs are dependent not only on clinical personnel, but also on support personnel, services such as diagnostic imaging, laboratory testing and blood banks, appropriate and functional equipment, and effective transport systems across large distances in all types of weather.

DISCUSSION

Levels of service

The safety of rural maternity services has been the subject of a number of studies over the past 20 years, and the weight of evidence supports the provision of local services, even in communities without access to local surgical services.^{5,6} Several recent studies have examined the importance of distance to services as it relates to outcomes and have shown that perinatal mortality, morbidity and intervention rates increase the farther women live from birthing services.^{7,8} While low-volume units face unique challenges, there is no evidence that a minimum number of deliveries is required to maintain competence.⁹ The question is not whether to provide birthing services or not, but what level of services is feasible and sustainable.

When a community is unable to sustain local services, almost all women will travel to access services elsewhere and, depending on the distance to the nearest referral centre, may be away from their homes and community from 36 weeks' gestation until they give birth. This separation can cause substantial degrees of stress for women and their families, and when socioeconomic vulnerability is a complicating factor, rates of adverse outcomes increase.^{7,10}

Other rural communities are able to provide medically supported maternity services. If surgical services are unavailable, the proportion of women delivering locally is lower because of both risk-management decisions and patient choice. Factors that influence patient choice are not always those that motivate their care providers.¹¹ Rural maternity care providers have identified many challenges, including determining and accepting risk, obtaining and maintaining competencies in low-volume environments and balancing women's needs against the realities of rural practice.¹² Evolving models of non-hospital-based maternity care will likely share similar challenges.

In communities with a surgical service the needs of women are more effectively met locally. In these communities, the majority (> 75% depending on provider model) of women give birth locally and the outcomes are good.^{7,13}

Models such as the Rural Birth Index have been developed to aid hospitals and health care planners to measure and quantify the need for, and feasibility of, local maternity services.¹⁴ This model was developed and works well in British Columbia and identifies both catchment populations that are underserved and overserved.¹⁴

Recommendation 4

4. While local access to surgical and anesthetic services is desirable, there is evidence that good outcomes can be sustained within an integrated perinatal care system without local access to operative delivery. There is evidence that the outcomes are better when women do not have to travel far from their communities. Access to an integrated perinatal care system should be provided for all women.

Impact of the loss of maternity services

When rural maternity services are lost, women are required to travel to ensure adequate access to maternity care providers and services. These women, who may need to leave their communities for a month or more, report financial, social and psychologic consequences.⁵ Financial costs almost always include accommodation and food in the referral community, often for a month or more in the period before and after the birth of the child.⁵ Additional financial constraints include loss of income and travel costs if the partner wishes to be present at the birth of the baby, arrangements for other children who may need to remain at home and the cost of phone calls to distant support networks.⁵ Studies in British Columbia have shown that women from some remote communities without maternity services spent an average of 29 days in the referral community at a cost of almost \$4000 per person.^{10,15}

Perhaps even more striking than the financial implications of having to travel to give birth are the social and psychologic costs. Women report feelings of isolation, separation and social disruption during what should be a joyful period in their lives.⁵ They may be overwhelmed by the need to navigate resources unfamiliar to them, the pain of missing friends and family members who could not be with

them in the referral community, and worries about how the newborn will integrate with other children left at home⁵ or the community in general.¹⁵ These social costs may be particularly acute for Aboriginal women because of their strong cultural ties to the land and their close-knit community values.¹⁵⁻¹⁷

Recommendation 5

5. The social and emotional needs of rural women must be considered in service planning. Women who are required to leave their communities to give birth should be supported both financially and emotionally.

Collaborative care and the rural maternity team

The long-term sustainability of a low-volume maternity unit depends on interprofessional respect, continuing education opportunities and collaborative models of practice that include all providers.¹⁸ Models based on multidisciplinary collaboration have been suggested as one solution to the declining number and changing nature of maternity care providers in Canada.¹⁹ Key elements of successful collaborative maternity programs have been described by the Multidisciplinary Collaborative Primary Maternity Care Project.²⁰ All rural maternity teams are unique, but they may include nurses, nurse practitioners, midwives, family physicians and specialist physicians, and they may be supported by health and social programs.

Registered nurses have been described as multi-specialists¹⁸ when they practise in rural and remote settings. They care for women in labour and birth, which demands complex knowledge and skills and a high degree of responsibility.²¹ If these skills are not used often, maintaining proficiency may be challenging,²² and programs and continuing education are important to ensure competence. The skill sets of maternity nursing are no different from other multispecialist roles, but also include the task of safeguarding women giving birth.²³ In low-volume units, a nurse may be the only person in the hospital, with a labouring woman, who has the expertise to evaluate normal progression with physicians and other nurses on call.²⁴ This requires the nurse to have the confidence to make decisions about what is normal in labour and to call for backup as required.

Regulated midwifery has expanded greatly across Canada. Rural midwives face the same challenges of professional isolation, unsustainable workload and difficulties in obtaining locum coverage

that other practitioners face.²⁵ Issues of transport and surgical backup are amplified in home deliveries, an important component of many midwifery practices. Funding and health care system design solutions have been proposed,²⁵ and there is an increasing recognition of the need for collaboration between other provider groups and midwives.²⁶

Greater awareness of the needs of Aboriginal women living in rural and remote areas, particularly the North, have brought a demand for low-risk maternity services, often based on care by registered midwives, registered Aboriginal midwives and traditional midwives. These programs have resulted in the return of birth to several Aboriginal communities across the country. Of great community importance, these programs have excellent medical and social outcomes.^{27,28} These programs strive to help communities “retain and restore” what is important from their own birth traditions, without losing the benefits of modern obstetric practice.²⁷ Although in areas of extremely low population density it is unrealistic to believe that all women can deliver in their home communities, it is important that Aboriginal, rural and remote women can access low-risk maternity care that reflects their experiences, expectations and culture.^{27,29} The importance of returning birth to the North and to Aboriginal communities has been acknowledged by several national organizations.^{30,31}

In the past decade, many medical communities have responded to the declining number of care providers by creating collaborative practice models. The most common model is a group of family physicians working in a shared prenatal clinic with a defined period of on-call responsibility.³²⁻³⁴ Both physicians and patients report a high level of satisfaction with these models,^{11,32-34} and outcomes are good.^{32,34} At least one community notes that group practice has led to the creation of a more supportive environment and the development of best practice protocols.³⁵

Communities that are unable to support sustainable surgical or obstetric specialist care, but that are large enough to justify local surgical services, can effectively be supported by GP-surgeons who provide only cesarean sections or broader surgical services. The evidence suggests that they make a significant contribution to equitable access to care for rural populations, and their patients have outcomes comparable to those of specialist surgeons and obstetricians.³⁵⁻³⁷ General practitioner-surgeons face many challenges, including accessing initial training, the lack of an accepted regulatory framework and limited continuing

Training for rural maternity care

A decision to practise in a rural region has been linked to a number of factors, including being from a rural area and having the opportunity to train in a rural area.^{49,50} Practitioners are most comfortable in environments that are similar to those in which they have trained. Early exposure to both rural environments and maternity care plays a key role in decision-making about practice scope and location.⁵¹ Many programs struggle to provide these experiences, but without them the strong base of generalism that rural health care is built on will be lost. The last decade has seen the opening of numerous new rural and northern training sites that bring increased opportunities to learn maternity care in a rural environment. Rural training sites face unique challenges, including increased cost;⁵² funding that accommodates these additional costs must be available to all professional programs.

All learners should have appropriate competencies for rural maternity care, such as interprofessional work, collaborative practice and a commitment to ongoing learning. Management of uncomplicated vaginal birth must remain a key competency for nursing, midwifery and family physician training. In some jurisdictions outside Canada, this has been designated an added or optional skill for family medicine residents.⁵³ To date, the Canadian family medicine residency curriculum has resisted similar streaming, instead insisting that all residents should be competent in normal vaginal deliveries.⁵⁴

Access to additional training in advanced skills, including cesarean section and obstetric anesthesia, is essential. Rural track maternity programs and fellowships in maternity care have been shown to increase the number of new physician graduates offering maternity care.^{55,56} Currently, training in performing cesarean sections is provided for family physicians at several residency sites in Canada. Training in broader general surgical skills is more difficult to access. Those wishing to train as GP-anesthetists have access at many sites to third-year programs accredited by the the College of Family Physicians of Canada; the standards for these programs are set by the Canadian Anesthesiologists' Society and the Society of Rural Physicians of Canada. Enhanced skills training for family physicians remains critical for rural maternity care.

Recommendations 10 to 12

10. Training of rural maternity health care providers

should include collaborative practice as well as the necessary clinical skills and competencies. Sites must be developed and supported to train midwives, nurses and physicians, and provide them with the skills necessary for rural maternity care. Training in rural and northern settings must be supported.

11. Generalist skills in maternity care, surgery and anesthesia are valued and should be supported in training programs in family medicine, surgery and anesthesia, as well as nursing and midwifery.
12. All physicians and nurses should be exposed in their training to maternity care, and basic competencies should be met.

Patient safety and continuing professional education

Comprehensive patient safety programs should be an integral part of rural maternity care. The characteristics of these safety programs have been well described: they should be comprehensive, patient focused and applied within a culture of safety.^{57,58} They should identify system failures, analyze the factors that contribute to the failures and redesign the care process to prevent errors in the future.⁵⁷ A key component is the review of events based on "a culture of openness to all relevant perspectives in which those involved in adverse events are treated as partners in learning";⁵⁹ these reviews should be carried out with an understanding of the rural environment.

To promote consistent and evidenced-based practice, continuing professional development programs must be available for rural caregivers. Although historically these programs have been delivered off-site and to each discipline separately, newer models involve locally delivered collaborative learning. Rural communities are ideally suited to this improved model because the health care professional teams are small, and strong collaboration is essential. Education that supports all members of the team to provide high-quality rural maternity care is optimal, so that the whole team has the same knowledge base. Locally delivered continuing professional development contributes to the culture of safety while building collaborative teams and ensuring that the content is relevant to the rural reality.

One example of a collaborative and locally provided patient safety program is Managing Obstetrical Risk Efficiently (MORE^{OB}).⁶⁰ This interdisciplinary program builds a culture of safety through the development of knowledge, skills, attitudes, behaviours and practices that make patient safety the priority for

professional development opportunities. Support from the dominant surgical specialist professions is varied, and GP-surgery has at times faced active resistance from the discipline of general surgery.³⁸

While only a small percentage of Canadian specialists practise in rural and remote communities, many rural maternity programs are reliant on specialist obstetricians and/or general surgeons who are often practising solo or in very small groups. Rural specialists report a high level of satisfaction with the support they receive locally, but very few feel supported by national organizations such as the Royal College of Physicians and Surgeons of Canada or the Canadian Medical Association.³⁹ Respondents to a survey expressed an overwhelming desire for relevant and accessible ongoing professional development and noted a lack of training opportunities.³⁹ Rural maternity care teams need to be supported by consulting urban specialists who are responsive and respectful, and who understand the rural reality.

Obstetric anesthesia services, delivered largely by GP-anesthetists, form a key component of rural maternity systems, and include not only epidurals administered during labour and anesthesia at cesarean section, but also support for neonatal resuscitation. Provision of a full-time elective epidural service is difficult for practitioners who wear many hats and work solo or in small groups.⁴⁰ Greater training and continuing professional development opportunities, as well as novel funding mechanisms, have been proposed as part of the solution.⁴¹

Health and social supports from early pregnancy through the postpartum and newborn periods are essential to the provision of quality care.^{42,43} Doula care has been shown to improve maternal and newborn outcomes.⁴⁴ Innovative models of community-based doula training have shown success, and engaging the human resources of rural communities has deep roots in Canada. It is essential that all rural women have access to supports such as prenatal educational, postpartum care and lactation support, even when local intrapartum services are not offered.

While differences in scope and remuneration models create barriers to true collaboration among different care provider groups, many communities have found ways to overcome them. Group practice models often include enhanced roles for nurses and nurse practitioners,^{32,33} thus reducing demands on family physicians who are also providing primary care, emergency department coverage and/or hospital care. The integration of midwifery care in rural communities provides new opportunities and new challenges.²⁵ Remuneration models that recognize

the level of responsibility and challenges faced by the rural accoucheur should be considered. It is also important to remove financial disincentives and regulatory barriers to shared care between the medical and midwifery professions such that collaborative practice can be encouraged.

Recommendations 6 to 8

6. Innovative interprofessional models should be implemented as part of the solution for high-quality, collaborative and integrated care for rural and remote women.
7. Registered nurses are essential to the provision of high-quality rural maternity care throughout pregnancy, birth and the postpartum period. Maternity nursing skills should be recognized as a fundamental part of generalist rural nursing skills.
8. Remuneration for maternity care providers should reflect the unique challenges and increased professional responsibility faced by providers in rural settings. Remuneration models should facilitate interprofessional collaboration.

Newborn care

Newborn care is an important part of any maternity care system. Approximately 10% of newborns will require resuscitation, and 1% will require extensive resuscitation, with at least one-half of these cases being unexpected.⁴⁵ Canadian guidelines recommend that “all health care facilities providing care for newborn infants must be able to resuscitate and stabilize such infants until transfer to another appropriate facility,” and that such care should be multidisciplinary and provided by trained staff with access to ongoing education and training.⁴⁶ In rural and remote settings, however, specialized pediatric and neonatal staff are rare. There is limited evidence regarding providers and outcomes of neonatal resuscitation in rural Canada, but some research suggests that levels of training and skill levels are lower than in larger centres.^{47,48} This gap, along with lower birth volumes and less access to specialized practitioners (e.g., respiratory therapy), highlights the increased need for local access to quality training and quality assurance programs in rural communities.

Recommendation 9

9. Practitioners skilled in neonatal resuscitation and newborn care should be regarded as essential to rural maternity care.

all caregivers. It promotes quality obstetric care and quality of life for caregivers, integrating high-reliability organization principles and using a foundation of current, evidence-based core clinical content. It adapts to local circumstances and all levels of care and caregivers, both urban and rural. Teamwork, respect and communication are improved by the team reviewing the core clinical content and sharing knowledge through audit, case review, emergency drills and other activities. Ultimately, a culture of patient safety is established. Research shows that maternal and newborn outcomes, as well as health care use, improved at hospitals adopting the 3-year program.⁶¹ Rural centres (including sites with as few as 10 deliveries per year) that have adopted the program have demonstrated improvement in knowledge, communication, teamwork and patient safety.

Recommendations 13 and 14

13. Quality improvement and outcome monitoring should be integral to all maternity care services.
14. Support must be provided for ongoing, collaborative, interprofessional, and locally provided continuing education and patient safety programs.

CONCLUSION

Rural maternity care services are under stress, and many rural and remote communities across Canada have seen local maternity services diminish and close. Rural women and families who have to travel to access maternity care experience increased levels of stress, increased personal costs and increased rates of adverse outcomes. Current health care policy does not adequately support rural nurses, doctors and midwives to meet the needs of rural women, and new approaches are needed to support collaborative, integrated and safe care for mothers and newborns in rural Canada.

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JOINT POSITION PAPER DÉCLARATION DE PRINCIPE COMMUNE

Soins de maternité en région rurale (sommaire)

English version on page 135

La version intégrale en français est affichée sur amc.ca/cjrm

La présente déclaration de principe commune a été rédigée par le Groupe de travail sur la déclaration de principe commune et approuvée par l'Association canadienne des sages-femmes, l'Association canadienne des infirmières et infirmiers en périnatalité et en santé des femmes, le Collège des médecins de famille du Canada, la Société des obstétriciens et gynécologues du Canada et la Société de la médecine rurale du Canada.

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Une étude de la littérature scientifique courante portant sur les soins de maternité pertinents pour les populations rurales vient appuyer les 14 recommandations formulées et approuvées par 5 organisations nationales de médecins, de sages-femmes et d'infirmières. Cette étude et ces recommandations visent à aider les fournisseurs de soins en obstétrique des milieux ruraux à continuer d'offrir des soins de qualité aux femmes de leurs communautés.

RECOMMANDATIONS

Les 14 recommandations suivantes ont été traduites à partir du document original en anglais, page 135.

1. Les femmes des communautés rurales et éloignées du Canada devraient recevoir des soins de maternité de grande qualité le plus près possible de chez elles.
2. Les soins de maternité en région rurale doivent être offerts de façon concertée, être axés sur la femme et sa famille, être adaptés aux différences culturelles et être prodigués de façon respectueuse.
3. Les services offrant des soins de maternité en région rurale devraient être soutenus par des politiques concrètes se conformant aux présentes recommandations.
4. Bien qu'un accès local à des services de chirurgie et d'anesthésie soit souhaitable, certaines données indiquent que l'obtention de bonnes issues peut être soutenue au sein d'un système intégré de soins périnataux ne disposant pas d'un accès local à des services d'accouchement opératoire. Certaines données indiquent que les issues sont meilleures lorsque les femmes n'ont pas à s'éloigner de leur communauté. L'accès à un système intégré de soins périnataux devrait être offert à toutes les femmes.
5. Les besoins sociaux et affectifs des femmes issues de régions rurales doivent être pris en considération dans le cadre de la planification des services. Les femmes qui doivent quitter leur communauté pour accoucher devraient être soutenues, et ce, tant sur le plan financier qu'affectif.
6. La mise en œuvre de modèles interprofessionnels novateurs devrait faire partie de la solution pour l'offre de soins concertés, intégrés et de grande qualité aux femmes des régions rurales et éloignées.
7. Les infirmières autorisées sont essentielles à l'offre de soins de maternité de grande qualité en région rurale tout au long de la grossesse, de l'accouchement et de la période postpartum. Les habiletés liées aux soins infirmiers de maternité devraient être reconnues comme étant une composante fondamentale des habiletés liées aux soins infirmiers généraux offerts en région rurale.
8. La rémunération des fournisseurs de soins de maternité devrait refléter les défis particuliers et la responsabilité

professionnelle accrue qui sont le lot des fournisseurs de soins en milieu rural. Les modèles de rémunération devraient faciliter la collaboration interprofessionnelle.

9. La présence de praticiens formés en réanimation et en soins néonataux s'avère essentielle à l'offre de soins de maternité en région rurale.
10. La formation des fournisseurs de soins de maternité en région rurale devrait aborder le concept de pratique concertée, ainsi que les techniques et habiletés cliniques nécessaires. Des établissements permettant de former des sages-femmes, des infirmières et des médecins et étant en mesure de leur inculquer les habiletés nécessaires à l'offre de soins de maternité en région rurale doivent être mis sur pied et soutenus. La formation en milieu rural et nordique doit être soutenue.
11. Les habiletés générales en matière de soins de maternité, de chirurgie et d'anesthésie sont précieuses et devraient être soutenues au sein des programmes de formation en médecine familiale, en chirurgie et en anesthésie, ainsi qu'en soins infirmiers et en pratique sage-femme.

12. Tous les médecins et toutes les infirmières devraient être exposés aux soins de maternité au cours de leur formation et acquérir des habiletés de base dans le domaine.

13. L'amélioration de la qualité et le suivi des issues devraient faire partie intégrante de tous les services de soins de maternité.
14. Les programmes de sécurité des patientes et de perfectionnement permanent continus, concertés, interprofessionnels et offerts localement doivent bénéficier d'un soutien.

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Intérêts concurrents : Aucuns déclarés.

LES MÉDECINS S'EXPRIMENT

La parole aux médecins — Lettres à la rédaction — Éditoriaux

Nous invitons les médecins à commenter les questions qui les intéressent. Faites parvenir vos textes à Suzanne Kingsmill, rédactrice administrative, *JCMR*, 45, boul. Overlea, C. P. 22015, Toronto (Ontario) M4H 1N9; cjrm@cjrm.net

Country cardiograms case 45

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*This article has been peer
reviewed.*

A 53-year-old woman presents to her local emergency department with a 2-hour history of first-episode sharp retrosternal chest pain with associated dyspnea, nausea and diaphoresis. The pain started while she attended a graveside funeral service for a close friend. The patient's cardiac risk factors include lifestyle-controlled hypertension; hypercholesterolemia, for which she has been prescribed pravastatin; and a positive family history. Physical examination reveals a fourth heart sound. The initial electrocardiogram (ECG) is unremark-

able; however, troponin levels are elevated. The pain persists in spite of medical therapy, and a subsequent ECG reveals diffuse T-wave inversions (Fig. 1). What diagnosis is most likely based on this ECG? What areas of the myocardium appear to be involved? What coronary arteries are involved? Based on this history, what other diagnosis should be considered? How should treatment be managed?

For the answer, see page 154.

Competing interests: None declared.

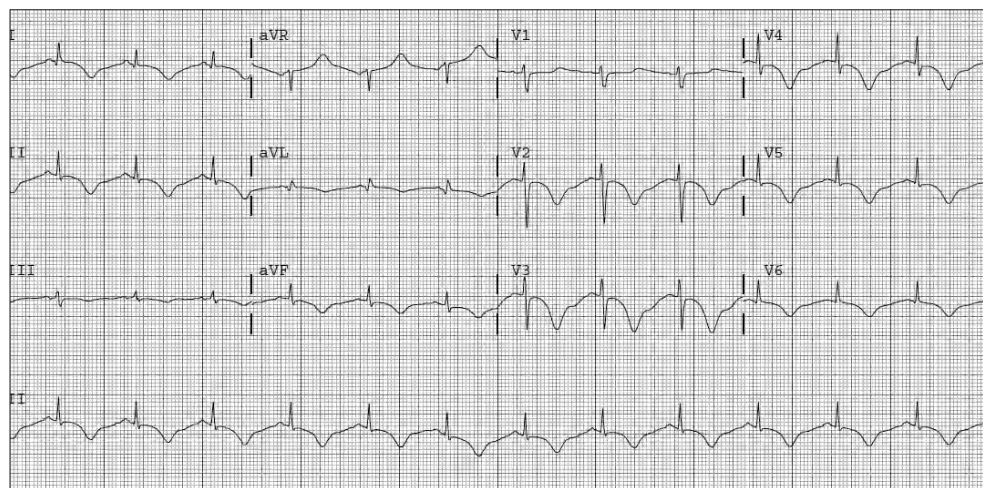


Fig. 1. Electrocardiogram of a 53-year-old woman with a first episode of retrosternal chest pain, showing T-wave inversions.

Caudal epidural injection

See related articles on pages 119, 127 and 148

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This article has been peer
reviewed.

Chronic low back pain is a ubiquitous problem. Epidural administration of steroids is one of our limited options. Although anesthesiologists might prefer the more familiar translumbar approach, caudal epidural injections are considered technically easier and safer, with minimal risk of inadvertent dural puncture.

A systematic review¹ found 18 randomized trials for caudal epidural injection. The evidence showed short- and long-term (> 6 mo) relief in chronic low back and lower extremity pain secondary to lumbar disc herniation, radiculitis or both, and discogenic pain without disc herniation or radiculitis. The review also included nonrandomized or case-control evidence for caudal epidural injections in managing low back pain from post-lumbar laminectomy syndrome and spinal stenosis.

Dr. Howe, a rural general practitioner with decades of experience with this procedure, offers his technique below.

Peter Hutten-Czapski, Scientific Editor

REFERENCE

1. Conn A, Buenaventura RM, Datta S, et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009;12:109-35.

Caudal epidural injection for back pain and sciatica can be performed by family physicians without special training as long as they follow the correct procedure.

INDICATIONS

- Caudal epidural injection can be considered for severe low back pain presenting as an emergency (after cord compression has been ruled out). If successful, it is the most effective form of analgesia and usually persists long after the local anesthetic would have worn off.
- The other indication is persistent low back or sciatic pain not responding to conservative measures.

CONTRAINDICATIONS

- Sensitivity to local anesthetic
- Sepsis at the injection site
- Anticoagulant therapy
- Theoretically, previous neurologic infection, because the injected fluid might restart the inflammation

ADVERSE EFFECTS

Adverse effects are rare but in theory include

- Infection
- Accidental spinal anesthetic, with or without hypotension, and spinal headache (if the dura is penetrated)
- Subperiosteal injection, which is not dangerous but is painful

- Temporary paralysis of the anal sphincter in the event of extensive superficial injection

In 50 000 injections using 50 mL of 0.5% procaine, Cyriax encountered 1 case of hypersensitivity, 2 of temporary paraplegia and 2 of chemical meningitis, and all 5 cases resolved spontaneously.¹

THEORY

The theca extends to about as low as the S1 level, so injections into the spinal canal below this level pass up extradurally and bathe the nerve roots.

EQUIPMENT

- 20 G spinal needle
- 10 mL syringe
- 3 mL syringe with a fine needle
- Alcohol wipes
- 80 mg methylprednisolone
- Local anesthetic (some experts recommend procaine, but bupivacaine or lidocaine are acceptable; I use 1%)
- Ink pen

PROCEDURE

Obtain consent after advising the patient of the rare possibility of adverse effects. Caution the patient that, although there is a good chance of immediate relief, the pain might get worse for a day or 2, even if the procedure is ultimately successful.

1. Have the patient lie in the prone position with a pillow under the symphysis pubis and buttocks exposed. If the pain is too severe to allow that position, the patient can lie on his or her side with hips flexed. Some physicians find it easier to palpate the landmarks with this position.
2. Draw up 9 mL of local anesthetic and 80 mg of methylprednisolone into the 10 mL syringe.
3. Feel for the 2 cornua of the sacral hiatus after separating the buttocks. There are 3 tricks if the cornua are not immediately obvious. One is to start below and move your finger up the dorsal surface of the coccyx until you encounter a slight "step." Another is to place the tip of your index finger over the anus, and the hiatus will be about the level of your proximal interphalangeal joint. A third trick is that the hiatus is at the point of a downward pointing equilateral triangle whose other 2 angles are the 2 posterior inferior iliac spines. I mark the cornua with a pen. Sterilize the skin with alcohol and allow it to dry.

4. Infiltrate the area with local anesthetic (with the 3 mL syringe and fine needle) in case you have to poke around a bit with the spinal needle, and use this to assess the angle of the lower sacrum.
5. Insert the spinal needle, with its stylet, into the space between the cornua on either side, the coccyx below and the arch of S5 above (Fig. 1). It may take a little manoeuvring to find the correct angle because it varies among patients, but it is roughly parallel to the body of S5 and very often horizontal or inclined slightly downward. Unless you get it exactly right, you may feel some resistance as the needle slides against bone.
6. Withdraw the stylet and wait to see if cerebrospinal fluid or blood drips out. If the former occurs, the patient is one of the rare few whose dura extends lower than usual and the injection must be abandoned to avoid giving a spinal anesthetic. If blood drips out, the needle can be repositioned to avoid an intravascular injection.
7. Assuming there is no leaking of cerebrospinal fluid, attach the 10 mL syringe containing local anesthetic and methylprednisolone and start to inject it slowly (Fig. 2). If you inject too quickly there is a danger of drowsiness from a pressure effect, so engage the patient in conversation as you inject. Place your other hand over the lower sacrum; if you feel the skin rise up your injection is too superficial.



Fig. 1. Inserting the needle.

8. As you continue the injection the patient may feel burning in 1 or both legs as the local anesthetic bathes the nerve roots, so, before you start, warn the patient that this might happen.
9. Remove the needle when all the material has

been injected and stuff a gauze swab in the natal cleft.

10. Have the patient wait a few minutes before getting up and walking. Any weakness will be syn-copal and not neurologic.



Fig. 2. Injecting anesthetic.

FOLLOW-UP

Because of the possibility of transient worsening of symptoms, it is best to wait a week or 2 to assess the results. If pain improves and later recurs, the injection can be repeated. In my experience, the intervals between injections typically lengthen, and usually fewer than 4 are needed.

Competing interests: None declared.

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RESOURCE

Cyriax JH, Cyriax PJ. *Cyriax's illustrated manual of orthopaedic medicine*. Oxford: Butterworth Heinemann; 1983. p. 226-30.

CALL FOR PAPERS

The *Canadian Journal of Rural Medicine (CJRM)* is a quarterly peer-reviewed journal available in print form and on the Internet. It is the first rural medical journal in the world indexed in Index Medicus, as well as MEDLINE/PubMed databases.

CJRM seeks to promote research into rural health issues, promote the health of rural and remote communities, support and inform rural practitioners, provide a forum for debate and discussion of rural medicine, provide practical clinical information to rural practitioners and influence rural health policy by publishing articles that inform decision-makers.

Material in the following categories will be considered for publication.

- Original articles: research studies, case reports and literature reviews of rural medicine (3500 words or less, not including references)
- Commentary: editorials, regional reviews and opinion pieces (1500 words or less)
- Clinical articles: practical articles relevant to rural practice. Illustrations and photos are encouraged (2000 words or less)
- Off Call articles: a grab-bag of material of general interest to rural doctors (e.g., travel, musings on rural living, essays) (1500 words or less).
- Cover: artwork with a rural theme

For more information please visit srpc.ca.

The occasional epidural steroid injection

See related articles on pages 119, 127 and 145

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This article has been peer
reviewed.

This description of an epidural steroid injection accompanies a related research article in this issue.¹

Epidural steroid injection for back pain is a procedure that a general practitioner–anesthetist, experienced in epidural anesthesia administration, may want to consider for treating back pain in appropriately selected patients. The procedure differs from a standard epidural (typically given in healthy, young pregnant women) in that the patient population typically has moderate to severe lumbar osteoarthritis, making the procedure technically more difficult.

Patients with lumbar spinal stenosis (in which neurogenic claudication is

relieved by forward flexion) and patients with lumbar disc herniation (which includes reproducible sciatica) could be considered candidates. The present supporting evidence for this procedure is weak, but it is sometimes suggested by orthopedic specialists when conservative or surgical options are limited.

PATIENT SELECTION

It might be wise to initially avoid selecting patients who have had back surgery, as the procedure is most challenging in these patients, and indwelling hardware always increases the risk of infection.

We evaluate the patient for interspinous ligament and quadratus lumborum trigger points, which can be treated effectively with tissue injections of lidocaine and do not need epidural steroids.²

THE PROCEDURE

As in any other epidural injection, the patient must be instructed to notify the physician if any paresthesia is experienced during needle advancement. If this occurs, the physician must realign the needle and change angles. No injection or advancement should be done until the needle is repositioned and any paresthesia is resolved. See Figures 1–6 for step-by-step instructions on performing the procedure.

AFTERCARE

Be cautious with mobilizing the patient afterward as some people are prone to



Fig. 1. The equipment is a standard epidural tray set-up (containing 17-gauge Tuohy loss-of-resistance needle, sterile preparation and lidocaine in a 25-gauge 1.5-inch needle), with no need for the catheter component or securing adhesives.



Fig. 2. We have the patient seated with lumbar spine in flexion. Using the iliac crest as a marker, we generally consider this to be L4-5 level.



Fig. 4. With the use of the Tuohy needle (with obturator) along the same tract, the epidural space is identified by using loss-of-resistance technique with a glass syringe or specific epidural loss-of-resistance syringe (included in disposable epidural kits). Loss of resistance at a more superficial depth than the actual epidural space may occur in patients with long-standing osteoarthritis (and variable bony architecture). If you feel this is occurring, try injecting 1–2 mL normal saline. If you regain resistance, you are in soft tissue and not yet at the epidural space.



Fig. 3. We infiltrate the skin and subcutaneous tissue with lidocaine to the depth, by feel, of the interspinous ligament. The transiliac-crest level may actually identify the L3-4 level more often (77% of cases)³ than the L4-5 level, even though the line radiographically correlates well with the L4-5 level.² Palpation and radiographic assessment may therefore differ in what levels are being identified, and identification of levels is affected by interobserver variability.⁴ We identify the space where most symptoms arise clinically or radiographically. If a fusion or graft exists at that level, we generally go 1 level above and try to avoid surgical scars.



Fig. 5. Continue to safely advance the needle to find the epidural space with loss of resistance.

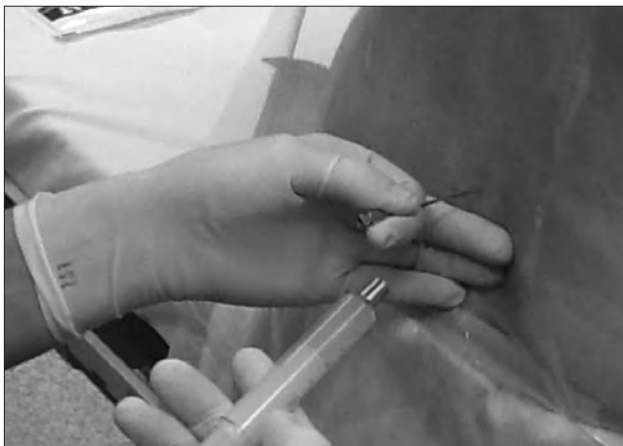


Fig. 6. Once the needle is correctly positioned, inject 80 mg methylprednisolone diluted to a total 5 mL solution with normal saline. Remove needle and apply a bandage.



Medical software for smartphones

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Several physicians who use smartphones, such as the Apple iPhone, have recently asked me where they can find useful medical software. This article discusses some of the best sources for medical software applications and some issues involved in downloading and using them.

SMARTPHONES

A smartphone is a cellphone that can also be used as a hand-held computer. Smartphones are available from many different manufacturers, with the models from Apple and BlackBerry being among the most popular.

OPERATING SYSTEM

The operating system (OS) is the master software program that controls all other functions. When purchasing medical software, be sure that the program is available for the OS used by your device. Major medical applications are usually available for more than one OS.

APPLICATIONS

Applications (“apps”) are software programs that can be downloaded and used on the smartphone. For physicians, the 2 most popular types of application are a general medical reference, such as The 5-Minute Clinical Consult, and a drug reference, such as Lexi-Drugs.

DOWNLOADING

Depending on the device and software vendor, applications may be downloaded by directly connecting the

smartphone to your desktop computer, by using a wireless network or by a cellular connection. Cellular connections are potentially more unstable than a wireless connection and may be subject to network connection charges.

HARDWARE MANUFACTURERS

Cellphone manufacturers usually provide information about where users of their product can download applications for their products, such as the iTunes Store for the Apple iPhone. If you use the search term “medical” on these websites, you will discover that most applications are designed for patients. Try limiting your search to a medical specialty or to the name of a software vendor (see Medical software vendors).

MEDICAL SOFTWARE VENDORS

To save time and effort, visit the websites of the major medical software vendors to see what they offer. Some popular applications, such as The 5-Minute Clinical Consult, are available from more than one vendor. Some vendors offer cost-saving packages that contain more than one application.

SKYSCAPE

Skyscape (www.skyscape.com) has more than 600 medical applications available for health care professionals. To narrow your search, click on the “Physicians” link and then select your specialty. Next, click the “View all” link to see all relevant products. The list is initially sorted by popularity, but you

fainting after procedures involving needles.

If the injection is effective, we typically see benefits within a few days and seldom encounter a "steroid flare." The relief of symptoms may last for months or longer. If the injection is initially effective and pain subsequently recurs, we consider a repeat injection at 3 months. We typically do not repeat injections that failed to relieve symptoms.

Competing interests: None declared.

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USBMIS

USBMIS (www.usbmis.com) has a variety of medical applications, including the drug database Tarascon Pharmacopoeia, which has some Canadian content. Click on “Products” in the top menu to view a list of applications that can be sorted by device or topic. Click on “All products” to limit a search by profession or device.

LEXICOMP

LexiComp (www.lexi.com) provides a number of comprehensive drug-related applications, plus a limited selection of other clinical applications, including The 5-Minute Clinical Consult. Its Lexi-Drugs application has good Canadian content. You can download an application that gives you a 30-day free trial of all their products.

PEPID

Pepid (www.pepid.com) provides packages of applications for family and emergency physicians. A 14-day free trial is available.

TARASCON

Tarascon (www.tarascon.com) provides the Tarascon Pharmacopoeia plus a limited selection of other medical applications.

EPOCRATES

The main Epocrates product is a drug database that is available in a free and a more extensive subscription edition (www.epocrates.com). It has a few other medical applications; its Canadian content was limited when last tested.

MEDSCAPE

The free Medscape Mobile application provides a drug database, a drug interaction checker, a disease reference, clinical procedures and specialty-focused medical news (www.medscape.com).

ITUNES — MEDICAL APPS

Access a list of the medical applications available on the iTunes website at itunes.apple.com/us/genre/ios-medical/id6020?mt=8.

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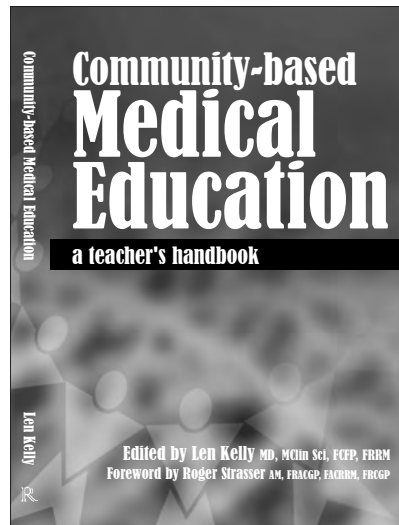
Competing interests: None declared.

BOOK REVIEW

Community-based Medical Education: A Teacher's Handbook. Len Kelly, editor. 247 pp. Radcliffe Publishing. 2012. Can\$59.50. ISBN-13: 978 184619 505 1

Len Kelly's book is timely. Although community-based medical education was all we ever did here in rural Canada, it only recently has had the legitimacy of being established as a primary path in medical training. This ascendancy in stature comes with an impressive, if not intimidating, number of learners and a wee bit of incentive to pull up one's socks.

Kelly has assembled a number of authors who speak to the contemporary challenges of teaching where we teach. The book starts with some basic chapters on contracting, monitoring and evaluation that are suited to all teachers, whether they are just starting out or they need a bit of spit and polish later in their careers. Then there are chapters that speak to



the hard topics. Instructing the difficult learner, teaching professionalism, mentoring in research, establishing boundaries and avoiding burnout.

The book's strengths are its chapters chock full of concepts, approaches and quite practical advice. Forming a structural base for that which we do, this book is a needed resource. It truly is a handbook.

Don't put down the book without letting your eyes wander to the excellent piece on teaching

generalism penned by Keith MacLellan. This summative chapter is a different gem. It puts medical education into a sociopolitical context in how we lost our way in medical training and how community-based education brings back the core values and competencies that our society needs.

The weaknesses of the handbook lie on the other side of the coin. A book with focused and practical concepts and advice does not make for an easy summertime read. It's not suited for a cover-to-cover read, at least not by this distracted rural doctor. I have too many interests and things to do, and teaching is just one of them.

Approach the book with a question — for example, about the international medical graduate learner, teaching about cultural safety or principles of procedural training — and you will not be disappointed.

Peter Hutten-Czapski, MD
Scientific editor, *CJRM*

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Country cardiograms case 45: Answer

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Interpretation of the electrocardiogram (ECG) shown in Figure 1 (on page 144) reveals normal sinus rhythm at a rate of about 75 beats/min. The QRS complex is normal in both duration (0.06 s) and axis (+30°). The corrected QT interval is prolonged (0.532 s). There is diffuse T-wave inversion in limb leads I, II, aVL and aVF, and precordial leads V2 through V6. There is no ST-segment elevation, nor are there any pathologic Q waves. The clinical history and T-wave inversion are suggestive of an ischemic etiology. Although in the absence of ST elevation one cannot comment on the coronary arterial distribution and precise myocardial territory involved, the diffuse nature of the ECG changes implies the involvement of a large portion of the myocardium. This would be unusual in occlusive atherosclerotic ischemic heart disease. However, it can occur in patients with a dominant left anterior descending artery that wraps around the apex of the heart, supplying the inferior wall as well as the anterolateral walls.

Based on the clinical history, ECG changes and laboratory investigations, the initial diagnosis was non-ST elevation myocardial infarction, and the patient was transferred to a tertiary care centre. She underwent urgent cardiac catheterization, which revealed patent coronary arteries with minimal atherosclerosis. The left ventriculogram showed severe hypokinesis with apical ballooning. Stress-induced cardiomyopathy was diagnosed.

Stress-induced cardiomyopathy is an increasingly recognized clinical entity that most often presents with signs and symptoms resembling acute coro-

nary syndrome or frank myocardial infarction. Patients may also present with dyspnea, as well as arrhythmia. Stress-induced cardiomyopathy was first described in Japan about 20 years ago, where it was given the name takotsubo (meaning “octopus trap” in Japanese) cardiomyopathy.¹ It is also commonly referred to as apical ballooning or broken heart syndrome.

Patients often present with ECG changes and modest elevations in troponin levels in the absence of demonstrable coronary arterial occlusion, stenosis or spasm. Common presenting ECG changes vary and can include ST-segment elevation, typically in the anterior precordial leads, T-wave inversion and other nonspecific abnormalities.² Stress-induced cardiomyopathy has been reported to account for about 1%–2% of patients presenting with suspected myocardial infarction.³

Patients with stress-induced cardiomyopathy are most commonly postmenopausal women experiencing an acute — often emotional — stressor. This cohort accounts for at least 80% of cases.⁴ Other reported acute triggers include intracranial trauma, hemorrhagic or ischemic strokes, medical illness, surgery and exogenous catecholamine administration.⁵ No trigger is identified in about one-third of patients.⁶ The underlying pathophysiology is not clear; however, the association with stressful events supports neurologic and catecholamine-mediated mechanisms. Although attempts have been made at developing diagnostic criteria,⁷ none have been formally adopted.

Because of the lack of reliable diagnostic criteria, patients who present to the emergency department with clinical

presentations suggestive of stress-induced cardiomyopathy should receive the usual treatment for acute coronary syndrome. This may involve fibrinolytic therapy, if clinically indicated. Diagnosis is often confirmed on cardiac catheterization, which reveals either normal coronary arteries or only mild atherosclerotic disease in the context of left ventricular apical ballooning with reduced systolic function.

The prognosis for stress-induced cardiomyopathy is good, with the average recovery time for left ventricular dysfunction being 2–3 weeks.⁵ The risk of recurrence is up to 10%.⁵ Although there are no specific treatments, complications such as heart failure and arrhythmia should be managed in the usual manner.

For the question, see page 144.

Competing interests: None declared.

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Country Cardiograms

Have you encountered a challenging ECG lately?

In most issues of *CJRM* an ECG is presented and questions are asked.

On another page, the case is discussed and the answer is provided.

Please submit cases, including a copy of the ECG, to Suzanne Kingsmill, Managing Editor, *CJRM*, 45 Overlea Blvd., P.O. Box 22015, Toronto ON M4H 1N9; cjrm@cjrm.net

Cardiogrammes ruraux

Avez-vous eu à décrypter un ECG particulièrement difficile récemment?

Dans la plupart des numéros du *JCMR*, nous présentons un ECG assorti de questions.

Les réponses et une discussion du cas sont affichées sur une autre page.

Veuillez présenter les cas, accompagnés d'une copy de l'ECG, à Suzanne Kingsmill, rédactrice administrative, *JCMR*, 45, boul. Overlea, C. P. 22015, Toronto (Ontario) M4H 1N9 ; cjrm@cjrm.net



salmeterol xinafoate / fluticasone propionate

[®]ADVAIR[®] DISKUS[®] / [®]ADVAIR[®]

salmeterol xinafoate/fluticasone propionate dry powder for inhalation/
salmeterol xinafoate/fluticasone propionate inhalation aerosol



Prescribing Summary

For complete prescribing information, please refer to the full Product Monograph at <http://www.gsk.ca>



Patient Selection Criteria

INDICATIONS AND CLINICAL USE

ASTHMA: ADVAIR[®] is indicated for the maintenance treatment of asthma in patients with reversible obstructive airways disease. ADVAIR[®]/ADVAIR[®] DISKUS[®] is not indicated for patients whose asthma can be managed by occasional use of a rapid onset, short duration, inhaled β_2 -agonist, or for patients whose asthma can be successfully managed by inhaled corticosteroids along with occasional use of a rapid onset, short duration, inhaled β_2 -agonist.

Long-acting β_2 -adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR[®] and ADVAIR[®] DISKUS[®], increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe ADVAIR[®] or ADVAIR[®] DISKUS[®] for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA.

Once asthma control is achieved and maintained, assess the patient at regular intervals and do not use ADVAIR[®] or ADVAIR[®] DISKUS[®] for patients whose asthma can be adequately controlled on low or medium dose inhaled corticosteroids. ADVAIR[®] contains a long-acting β_2 -agonist and should not be used as a rescue medication. To relieve acute asthmatic symptoms, a rapid onset, short duration inhaled bronchodilator (e.g. salbutamol) should be used.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): ADVAIR[®] 250 DISKUS[®] and ADVAIR[®] 500 DISKUS[®] are indicated for the maintenance treatment of COPD, including emphysema and chronic bronchitis, in patients where the use of a combination product is considered appropriate. ADVAIR[®] DISKUS[®] should not be used as a rescue medication. Physicians should reassess patients several months after the initiation of ADVAIR[®] DISKUS[®] and if symptomatic improvement has not occurred, ADVAIR[®] DISKUS[®] should be discontinued.

Geriatrics: There is no need to adjust the dose in elderly patients.

Pediatrics (< 4 years of age): At present, there is insufficient clinical data to recommend the use of ADVAIR[®] DISKUS[®] in children younger than 4 years of age and the use of ADVAIR[®] inhalation aerosol in children younger than 12 years of age.

CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.
- Patients with IgE mediated allergic reactions to lactose (which contains milk protein) or milk (ADVAIR[®] DISKUS[®] users only).
- Patients with cardiac tachyarrhythmias.
- Patients with untreated fungal, bacterial or tuberculous infections of the respiratory tract.
- In the primary treatment of status asthmaticus or other acute episodes of asthma, or in patients with moderate to severe bronchiectasis.



Safety Information

WARNINGS AND PRECAUTIONS

General: Information concerning a study regarding salmeterol, a component of ADVAIR[®]/ADVAIR[®] DISKUS[®]

ASTHMA-RELATED DEATH

Long-acting β_2 -adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR[®] and ADVAIR[®] DISKUS[®], increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of salmeterol (SEREVENT[®] Inhalation Aerosol) or placebo added to patients usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol (13 deaths out of 13, 176 patients treated for 28 weeks on salmeterol versus 3 deaths out of 13, 179 patients on placebo). Post-hoc analysis of the SMART trial data suggests that the risks may be lower in patients who were using inhaled corticosteroids (ICS) at study entry. However, these post-hoc analysis results are not conclusive.

Currently available clinical data are inadequate to determine whether concurrent use of inhaled corticosteroids mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe ADVAIR[®] or ADVAIR[®] DISKUS[®] for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and do not use ADVAIR[®] or ADVAIR[®] DISKUS[®] for patients whose asthma can be adequately controlled on low or medium dose inhaled corticosteroids.

ADVAIR[®] should not be used to treat acute symptoms of asthma. It is crucial to inform patients of this and prescribe rapid onset, short duration inhaled bronchodilator (e.g., salbutamol) to relieve the acute symptoms of asthma. Patients should be clearly instructed to use rapid onset, short duration, inhaled β_2 -agonists only for symptomatic relief if they develop asthma symptoms while taking ADVAIR[®]. When beginning treatment with ADVAIR[®], patients who have been taking rapid onset, short duration, inhaled β_2 -agonists on a regular basis (e.g., q.i.d) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief if they develop acute symptoms of asthma while taking ADVAIR[®].

Discontinuation: Treatment with inhaled corticosteroids should not be stopped abruptly in patients with asthma due to risk of exacerbation. In this case, therapy should be titrated down gradually, under physician supervision. For patients with COPD, cessation of therapy may be associated with symptomatic decompensation and should be supervised by a physician.

Cardiovascular And Other Effects: Although clinically not significant, a small increase in QTc interval has been reported with therapeutic doses of salmeterol. It is not known if this becomes clinically significant when concomitant medications causing similar effects are prescribed and/or in the presence of heart diseases, hypokalemia, or hypoxia. Large doses of inhaled or oral salmeterol (12 to 20 times the recommended dose) have been associated with clinically significant prolongation of the QTc interval, which has the potential for producing ventricular arrhythmias.

Fatalities have been reported following excessive use of aerosol preparations containing sympathomimetic amines, the exact cause of which is unknown. Cardiac arrest was reported in several instances.

No clinically significant effect on the cardiovascular system is usually seen after the administration of inhaled salmeterol in recommended doses. Cardiovascular effects such as increased blood pressure and heart rate may occasionally be seen with all sympathomimetic drugs, especially at higher than therapeutic doses. Central nervous system effects (increased excitement) can occur after the use of salmeterol. Occurrence of cardiovascular or central nervous system effects may require discontinuation of the drug. For this reason, salmeterol xinafoate/fluticasone propionate, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines.

In individual patients any β_2 -adrenergic agonist may have a clinically significant cardiac effect. As has been described with other beta-adrenergic agonist bronchodilators, clinically significant changes in systolic and/or diastolic blood pressure, pulse rate, and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with salmeterol.

Ear/Nose/Throat: Symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported rarely in patients receiving salmeterol.

Endocrine And Metabolism (Systemic Steroid Replacement by Inhaled Steroid): Particular care is needed in patients who are transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer. For the transfer of patients being treated with oral corticosteroids, inhaled corticosteroids should first be added to the existing oral steroid therapy which is then gradually withdrawn.

Patients with adrenocortical suppression should be monitored regularly and the oral steroid reduced cautiously. Some patients transferred from other inhaled steroids or oral steroids remain at risk of impaired adrenal reserve for a considerable time after transferring to inhaled fluticasone propionate. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery or infections, particularly gastroenteritis. Although inhaled fluticasone propionate may provide control of asthmatic symptoms during these episodes, it does not provide the systemic steroid which is necessary for coping with these emergencies. The physician may consider supplying oral steroids for use in times of stress (e.g. worsening asthma attacks, chest infections, and surgery).

During periods of stress or a severe asthmatic attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume systemic steroids immediately and to contact their physician for further instruction. These patients should also be instructed to carry a warning card indicating that they may need supplementary systemic steroids during periods of stress or a severe asthma attack. To assess the risk of adrenal insufficiency in emergency situations, routine tests of adrenal cortical function, including measurement of early morning and evening cortisol levels, should be performed periodically in all patients. An early morning resting cortisol level may be accepted as normal only if it falls at or near the normal mean level.

Systemic Effects: Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods; these effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, and adrenal suppression,

growth retardation in children and adolescents, decrease in bone mineral density (BMD), cataract and glaucoma. It is important therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control is maintained.

The long-term effects of fluticasone propionate in human subjects are still unknown. The local effect of the drug on developmental or immunologic processes in the mouth, pharynx, trachea, and lungs is unknown. There is also no information about the possible long-term systemic effects of the agent.

Long-term use of orally inhaled corticosteroids may affect normal bone metabolism resulting in a loss of bone mineral density. In patients with major risk factors for decreased bone mineral content, such as chronic alcohol use, tobacco use, age, sedentary lifestyle, strong family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants and corticosteroids), ADVAIR® may pose an additional risk.

Effects of treatment with ADVAIR® DISKUS® 50/500 mcg, fluticasone propionate 500 mcg, salmeterol 50 mcg, or placebo on BMD was evaluated in a subset of 658 patients (females and males 40 to 80 years of age) with COPD in a 3 year study (SC030003). BMD evaluations were conducted at baseline and at 48, 108 and 158 weeks. There were no significant differences between any of the treatment groups at 3 years. A slight reduction in BMD measured at the hip was observed in all treatment groups (ADVAIR® DISKUS® -3.2%, fluticasone propionate -2.9%, salmeterol -1.7%, placebo -3.1%). Fracture risk was estimated for the entire population of patients with COPD in study SC030003 (N=6,184). There were no significant differences between any of the treatment groups. The probability of a fracture over 3 years was 6.3% for ADVAIR® DISKUS®, 5.4% for fluticasone propionate, 5.1% for salmeterol, and 5.1% for placebo.

During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving intranasal or inhaled fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side-effects.

The results of a drug interaction study conducted in healthy subjects indicated that concomitant use of systemic ketoconazole (a strong cytochrome P450 3A4 inhibitor) increased exposure to salmeterol in some subjects. This increase in plasma salmeterol exposure may lead to prolongation in the QTc interval. Due to the potential increased risk of cardiovascular adverse events, the concomitant use of salmeterol with ketoconazole is not recommended. Caution should also be exercised when other CYP3A4 inhibitors are co-administered with salmeterol (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin).

Metabolic Effects: Doses of the related β_2 -adrenoceptor agonist salbutamol, when administered intravenously, have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis. Administration of β_2 -adrenoceptor agonists may cause a decrease in serum potassium, possibly through intracellular shunting, which has the potential to increase the likelihood of arrhythmias. The effect is usually seen at higher therapeutic doses and the decrease is usually transient, not requiring supplementation. Therefore, salmeterol/fluticasone propionate should be used with caution in patients predisposed to low levels of serum potassium.

The possibility of impaired adrenal response should always be borne in mind in emergency and elective situations likely to produce stress and appropriate corticosteroid treatment must be considered.

Certain individuals can show greater susceptibility to the effects of inhaled corticosteroid than do most patients.

In common with other beta-adrenergic agents, salmeterol can induce reversible metabolic changes (hyperglycemia, hypokalemia). There have been very rare reports of increases in blood glucose levels and this should be considered when prescribing to patients with a history of diabetes mellitus.

There is an enhanced effect of corticosteroids on patients with hypothyroidism.

Hematologic (Eosinophilic Conditions): In rare cases, patients on inhaled fluticasone propionate may present with systemic eosinophilic conditions, with some patients presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition that is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction and/or withdrawal of oral corticosteroid therapy following the introduction of fluticasone propionate. Cases of serious eosinophilic conditions have also been reported with other inhaled corticosteroids in this clinical setting. Physicians should be alerted to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal relationship between fluticasone propionate and these underlying conditions has not been established.

Hepatic/Biliary/Pancreatic: There is an enhanced effect of corticosteroids on patients with cirrhosis.

Hypersensitivity: Immediate hypersensitivity reactions may occur after administration of salmeterol, as demonstrated by rare cases of urticaria, angioedema, rash and bronchospasm, and very rare cases of anaphylactic reactions, anaphylactic shock.

Immune (Candidiasis): Therapeutic dosages of fluticasone propionate frequently cause the appearance of *Candida albicans* (thrush) in the mouth and throat. The development of pharyngeal and laryngeal candidiasis is a cause for concern because the extent of its penetration into the respiratory tract is unknown. Patients may find it helpful to rinse the mouth and gargle with water after using ADVAIR®. Symptomatic candidiasis can be treated with topical anti-fungal therapy while continuing to use ADVAIR®.

Infection: Corticosteroids may mask some signs of infection and new infections may appear. A decreased resistance to localised infection has been observed during corticosteroid therapy. This may require treatment with appropriate therapy or stopping the administration of fluticasone propionate until the infection is eradicated. Patients who are on drugs that suppress the immune system are more susceptible

to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with intramuscular pooled immunoglobulin (IG) may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

For patients with asthma or COPD, consideration should be given to additional corticosteroid therapy and to antibiotics if an exacerbation is associated with an infection.

For COPD patients, it is important that even mild chest infections be treated immediately since these patients may be more susceptible to damaging lung infections than healthy individuals. Patients should be instructed to contact their physician as soon as possible if they suspect an infection. Physicians should recommend that COPD patients receive an annual influenza vaccination.

In a 3 year study of 6,184 patients with COPD (SC030003) there was an increased reporting of any adverse event of pneumonia in patients receiving ADVAIR® 50/500 mcg compared with placebo (16% on ADVAIR® DISKUS® 50/500 mcg, 14% on fluticasone propionate 500 mcg, 11% on salmeterol 50 mcg and 9% on placebo). Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of pneumonia and exacerbations frequently overlap.

Ophthalmologic: For patients at risk, monitoring of ocular effects (cataract and glaucoma) should also be considered in patients receiving maintenance therapy with ADVAIR®.

Effects of treatment with ADVAIR® DISKUS® 50/500 mcg, fluticasone propionate 500 mcg, salmeterol 50 mcg, or placebo on development of cataracts or glaucoma was evaluated in a subset of 658 patients with COPD in a 3 year (SC030003) study. Ophthalmic examinations were conducted at baseline and at 48, 108 and 158 weeks. The presence of cataracts and glaucoma at baseline was similar across treatment groups (61% to 71% and 5% to 8%, respectively). New cataracts were diagnosed in all treatment groups (26% on ADVAIR® DISKUS® 50/500 mcg, 17% on fluticasone propionate, 15% on salmeterol, and 21% on placebo). A few new cases of glaucoma were diagnosed (2% on ADVAIR® DISKUS® 50/500 mcg, 5% on fluticasone propionate, none on salmeterol, and 2% on placebo). There were no significant differences in the development of glaucoma or cataracts between any of the treatment groups.

Respiratory: As with other inhalation therapy, paradoxical bronchospasm may occur characterized by an immediate increase in wheezing after dosing. This should be treated immediately with a rapid onset, short duration inhaled bronchodilator (e.g. salbutamol) to relieve acute asthmatic symptoms. ADVAIR® should be discontinued immediately, the patient assessed, and if necessary, alternative therapy instituted.

Special Populations:

Use In Women

Pregnant Women: There are no adequate and well-controlled studies with ADVAIR® in pregnant women. ADVAIR® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In animal studies, some effects on the fetus, typical for a beta-agonist, occurred at exposure levels substantially higher than those that occur with therapeutic use. Extensive use of other beta-agonists has provided no evidence that effects in animals are relevant to human use.

Like other glucocorticoids, fluticasone propionate is teratogenic to rodent species. Adverse effects typical of potent corticosteroids are only seen at high systemic exposure levels; administration by inhalation ensures minimal systemic exposure. The relevance of these findings to humans has not yet been established since well-controlled trials relating to fetal risk in humans are not available. Infants born of mothers who have received substantial doses of glucocorticoids during pregnancy should be carefully observed for hypoadrenalism.

Use in Labour and Delivery: There are no well-controlled human studies that have investigated effects of salmeterol on preterm labour or labour at term. Because of the potential for beta-agonist interference with uterine contractility, use of ADVAIR® during labour should be restricted to those patients in whom the benefits clearly outweigh the risks.

Nursing Women: Plasma levels of salmeterol after inhaled therapeutic doses are very low (85 to 200 pg/mL) in humans and therefore levels in milk should be correspondingly low. Studies in lactating animals indicate that salmeterol is likely to be secreted in only very small amounts in breast milk. Glucocorticoids are excreted in human milk. The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration, there was evidence of fluticasone propionate in the breast milk. However, plasma levels in patients following inhaled fluticasone propionate at recommended doses are likely to be low.

Since there is no experience with use of ADVAIR® by nursing mothers, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatrics: (≥ 4 years of age): In adolescents and children, the severity of asthma may vary with age and periodic reassessment should be considered to determine if continued maintenance therapy with ADVAIR® is still indicated.

The safety and efficacy of ADVAIR® DISKUS® in children younger than 4 years of age have not been established. The safety and efficacy of ADVAIR® inhalation aerosol in children younger than 12 years of age have not been established.

Geriatrics: As with other β_2 -agonists, special caution should be observed when using salmeterol in elderly patients who have concomitant cardiovascular disease that could be adversely affected by

this class of drug. Based on available data, no adjustment of salmeterol dosage in geriatric patients is warranted.

Monitoring And Laboratory Tests (Monitoring Control of Asthma or COPD): ADVAIR® should not be introduced in acutely deteriorating asthma or COPD, which is a potentially life threatening condition. Increasing use of rapid onset, short duration inhaled bronchodilators to control symptoms indicates deterioration of asthma control. Sudden and progressive deterioration in asthma control is potentially life-threatening and the treatment plan should be re-evaluated. Also, where current dosage of ADVAIR® has failed to give adequate control of reversible obstructive airways disease the patient should be reviewed by a physician. Before introducing ADVAIR®, adequate education should be provided to the patient on how to use the drug and what to do if asthma flares up.

During long-term therapy, HPA axis function and haematological status should be assessed periodically. For patients at risk, monitoring of bone and ocular effects (cataract and glaucoma) should also be considered in patients receiving maintenance therapy with ADVAIR®. It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

As with other inhalation therapy paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a rapid onset, short duration inhaled bronchodilator. ADVAIR® should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

The type and severity of adverse reactions associated with salmeterol xinafoate and fluticasone propionate may be expected with ADVAIR®. There is no incidence of additional adverse events following combined administration of the two compounds.

Salmeterol Xinafoate: The pharmacological side effects of β_2 -agonist treatment, such as tremor, subjective palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy.

Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles) may occur in some patients.

There have been reports of arthralgia and hypersensitivity reactions, including rash, urticaria, bronchospasm, edema, angioedema, anaphylactic reaction and anaphylactic shock.

There have been reports of oropharyngeal irritations as well as common reports of muscle cramps. Symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported rarely in patients receiving salmeterol.

Clinically significant changes in blood glucose and/or serum potassium were seen rarely during clinical studies with long-term administration of salmeterol at recommended doses.

Fluticasone Propionate: In general, inhaled corticosteroid therapy may be associated with dose dependent increases in the incidence of ocular complications, reduced bone density, suppression of HPA axis responsiveness to stress, and inhibition of growth velocity in children. Such events have been reported rarely in clinical trials with fluticasone propionate.

Possible systemic effects include Cushing's syndrome, Cushingoid features and adrenal suppression. Glaucoma may be exacerbated by inhaled corticosteroid treatment. In patients with established glaucoma who require long-term inhaled corticosteroid treatment, it is prudent to measure intraocular pressure before commencing the inhaled corticosteroid and to monitor it subsequently. In patients without established glaucoma, but with a potential for developing intraocular hypertension (e.g. the elderly), intraocular pressure should be monitored at appropriate intervals.

In elderly patients treated with inhaled corticosteroids, the prevalence of posterior subcapsular and nuclear cataracts is probably low but increases in relation to the daily and cumulative lifetime dose. Cofactors such as smoking, ultraviolet B exposure, or diabetes may increase the risk. Children may be less susceptible.

A reduction of growth velocity in children or teenagers may occur as a result of inadequate control of chronic diseases such as asthma or from use of corticosteroids for treatment. Physicians should closely follow the growth of children and adolescents taking corticosteroids by any route and weigh the benefits of corticosteroid therapy and asthma control against the possibility of growth suppression if any child's or adolescent's growth appears slowed.

Osteoporosis and fracture are the major complications of long-term treatment with parenteral or oral steroids. Inhaled corticosteroid therapy is also associated with dose-dependent bone loss although the degree of risk is very much less than with oral steroid. This risk may be offset by estrogen replacement in post-menopausal women, and by titrating the daily dose of inhaled steroid to the minimum required to maintain optimal control of respiratory symptoms. It is not yet known whether the peak bone density achieved during youth is adversely affected if substantial amounts of inhaled corticosteroid are administered prior to 30 years of age.

Failure to achieve maximal bone density during youth could increase the risk of osteoporotic fracture when those individuals reach 60 years of age and older. Hoarseness and candidiasis (thrush) of the mouth and throat can occur in some patients receiving inhaled fluticasone propionate. These may be relieved by rinsing the mouth and gargling with water after use of ADVAIR®. Symptomatic candidiasis can be treated with topical anti-fungal therapy while still continuing with ADVAIR®.

There have been uncommon reports of cutaneous hypersensitivity reactions. There have also been rare reports of hypersensitivity reactions manifesting as angioedema (mainly facial and oropharyngeal edema), respiratory symptoms (dyspnea and/or bronchospasm) and very rarely, anaphylactic reactions. There have been very rare reports of anxiety, sleep disorders and behavioural changes, including hyperactivity and irritability (predominantly in children and adolescents)

Eosinophilic Conditions: In rare cases, patients on inhaled fluticasone propionate may present with systemic eosinophilic conditions, with some patients presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition that is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction and/or withdrawal of oral corticosteroid therapy following the introduction of fluticasone propionate. Cases of serious eosinophilic conditions have also been reported with other inhaled corticosteroids in this clinical setting. Physicians should be alerted to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal relationship between fluticasone propionate and these underlying conditions has not been established.

Asthma: Long-acting β_2 -adrenergic agonists, such as salmeterol, one of the active ingredients in ADVAIR® and ADVAIR® DISKUS®, increase the risk of asthma-related death. Data from a large, placebo-controlled US study that compared the safety of salmeterol (SEREVENT® Inhalation Aerosol) or placebo added to usual asthma therapy showed an increase in asthma-related death in patients receiving salmeterol. Post-hoc analysis of the SMART trial data suggests that the risks may be lower in patients who were using inhaled corticosteroids (ICS) at study entry. However, these post-hoc analysis results are not conclusive. Currently available clinical data are inadequate to determine whether concurrent use of inhaled corticosteroids mitigates the increased risk of asthma-related death from LABA.

Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients.

Clinical Trial Adverse Drug Reactions

To report an adverse event, you may notify Health Canada by phone at 1-866-234-2345, or by toll-free fax at 1-866-678-6789 or by email at cadmp@hc-sc.gc.ca.

Asthma

Use in adolescents and adults: There have been very rare reports of anxiety, sleep disorders and behavioural changes including hyperactivity and irritability (predominantly in children and adolescents). There have been uncommon reports of contusions (skin bruising).

ADVAIR® DISKUS®: In clinical trials involving 1824 adult and adolescent patients, the most commonly reported adverse events with the combination salmeterol xinafoate/fluticasone propionate ADVAIR® were: hoarseness/dysphonia, throat irritation, headache, candidiasis of mouth and throat and palpitations (see Table 1).

ADVAIR® Inhalation Aerosol: In clinical trials, the most commonly reported adverse events with the combination salmeterol xinafoate/fluticasone propionate inhalation aerosol were: hoarseness/dysphonia, throat irritation and headache. All other adverse events with a reasonable possibility of being related to study drug were reported in $\leq 1\%$ of subjects (see Table 2)

Use in children: A total of 257 pediatric patients participated in the clinical development programme and received either the combination 50 mcg salmeterol xinafoate/100 mcg fluticasone propionate ADVAIR® or concurrent therapy (with salmeterol and fluticasone propionate administered via separate inhalers). Only one drug-related adverse event, candidiasis, was reported with an incidence of 2% or more in the ADVAIR® group. The combination product was generally well tolerated and the safety profile was comparable to that observed in the concurrent therapy group.

There have been very rare reports of anxiety, sleep disorders and behavioural changes including hyperactivity and irritability (predominantly in children and adolescents).

COPD

Clinical trial adverse drug reaction data is provided for two 24-week studies, a 52-week study and a 3-year study.

24-week studies: In clinical trials involving 2054 adults, the most commonly reported adverse events with ADVAIR® DISKUS® after 24 weeks were: upper respiratory tract infection, throat irritation, headache and musculoskeletal pain (see Table 3). These adverse reactions were mostly mild to moderate in severity.

Other COPD Clinical Trial Adverse Drug Reactions (1-3%)

Cardiovascular: arrhythmias, hypertension, palpitations

Drug Interaction, Overdose and Trauma: contusions, fractures, hematomas, lacerations and wounds

Ear/Nose/Throat: ear/nose/throat infections, ear/nose/throat signs and symptoms, ear signs and symptoms, epistaxis, laryngitis, nasal sinus disorders, pharyngitis/throat infections, rhinorrhea/post nasal drip, sputum abnormalities

Endocrine and Metabolism: diabetes mellitus, hypothyroidism

Gastrointestinal: constipation, dental discomfort and pain, diverticulosis, dyspeptic symptoms, gastrointestinal infections, gum signs and symptoms, hyposalivation, oral discomfort and pain; oral lesions, regurgitation and reflux

Hepatic/Biliary/Pancreatic: abnormal liver function tests

Immune: bacterial infections, candidiasis unspecified site, viral infections

Neurologic: anxiety, situational disorders, sleep disorders, syncope, tremors, vertigo

Non-Site Specific: bone and skeletal pain, edema and swelling, non-site specific pain, non-specific condition, soft tissue injuries

Ophthalmologic: dry eyes, eye infections, lacrimal disorders, ocular pressure disorders, visual disturbances

Per-Operative Considerations: postoperative complications

Respiratory: breathing disorders, bronchitis, lower respiratory hemorrhage, lower respiratory signs and symptoms, pneumonia

Skin: fungal skin infections and skin infections

52-week study: After 52 weeks of treatment with ADVAIR® DISKUS® (50/500 mcg), fluticasone propionate 500 mcg, salmeterol 50 mcg and placebo in 1465 patients with COPD, the most commonly reported drug related adverse event was candidiasis of the mouth and throat (ADVAIR® DISKUS®

50/500 mcg, 6%; fluticasone propionate 500 mcg, 6%; salmeterol 50 mcg, 1%; placebo, 1%.

3-year study: Study SC030003 provided safety data on 6,184 patients with moderate to severe COPD who were randomized and received at least one dose of study medication and treated for up to 3 years; defined as the Safety population. The safety profile of ADVAIR® over the three-year treatment period was comparable to that seen in previous studies of shorter duration, confirming the long-term tolerability of ADVAIR®. All three active treatments were well tolerated and the adverse events reported were generally those expected based on clinical experience with these treatments, with the exception of pneumonia. The estimated 3 year probability of having pneumonia reported as an adverse event was 12.3% for placebo, 13.3% for salmeterol, 18.3% for fluticasone propionate and 19.6% for ADVAIR® (Hazard ratio for ADVAIR® vs placebo: 1.64, 95% CI: 1.33 to 2.01, $p < 0.001$). There was no increase in pneumonia related deaths for ADVAIR®; deaths while on treatment that were adjudicated as primarily due to pneumonia were 7 for placebo, 9 for salmeterol, 13 for fluticasone propionate and 8 for ADVAIR®. There was no significant difference in probability of bone fracture (5.1% placebo, 5.1% salmeterol, 5.4% fluticasone propionate and 6.3% ADVAIR®; Hazard ratio for ADVAIR® versus placebo: 1.22, 95% CI: 0.87 to 1.72, $p = 0.248$). The incidence of adverse events of eye disorders, bone disorders, and HPA axis disorders was low and there was no difference observed between treatments. There was no evidence of an increase in cardiac events for ADVAIR®, salmeterol, and fluticasone propionate.

Post-Market Adverse Drug Reactions: There have been uncommon reports of cutaneous hypersensitivity reactions. There have also been rare reports of hypersensitivity reactions manifesting as angioedema (mainly facial and oropharyngeal edema), respiratory symptoms (dyspnea and/or bronchospasm) and very rarely, anaphylactic reactions, anaphylactic shock.

There have been very rare reports of anxiety, sleep disorders and behavioural changes, including hyperactivity and irritability (predominantly in children and adolescents). Very rarely, hyperglycemia and hypertension have been reported.

Particularly with previous or concurrent use of systemic steroids (e.g., IV or oral), there have also been very rare cases of osteonecrosis reported.

DRUG INTERACTIONS

Overview

Use ADVAIR® with caution in patients receiving other medications causing hypokalemia and/or increased QTc interval (diuretics, high dose steroids, anti-arrhythmics, astemizole, terfenadine) since cardiac and vascular effects may be potentiated.

Salmeterol Xinafoate: Co-administration of repeat dose ketoconazole (a cytochrome P450 3A4 inhibitor) and salmeterol in healthy subjects resulted in a significant increase in plasma salmeterol exposure (1.4-fold increase in C_{max} and 15-fold increase in AUC). This increase in plasma salmeterol exposure may cause a prolongation of the QTc interval.

Fluticasone Propionate: Under normal circumstances, low plasma concentrations of fluticasone propionate are achieved after inhaled dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome P450 3A4 in the gut and liver. Hence, clinically significant drug interactions involving fluticasone propionate are unlikely.

A drug interaction study of intranasal fluticasone propionate in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can greatly increase fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving intranasal or inhaled fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side-effects. This study has shown that other inhibitors of cytochrome P450 3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to fluticasone propionate without notable reductions in serum cortisol concentrations. However, there have been a few case reports during world-wide post-market use of adrenal cortisol suppression associated with concomitant use of azole anti-fungals and inhaled fluticasone propionate. Therefore, care is advised when co-administering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole) as there is potential for increased systemic exposure to fluticasone propionate.



Administration

DOSAGE AND ADMINISTRATION

Dosing Considerations: Long-acting β_2 -adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR® and ADVAIR® DISKUS®, increase the risk of asthma-related death. Therefore, when treating patients with asthma, physicians should only prescribe ADVAIR® or ADVAIR® DISKUS® for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA.

Once asthma control is achieved and maintained, assess the patient at regular intervals and do not use ADVAIR® or ADVAIR® DISKUS® for patients whose asthma can be adequately controlled on low or medium dose inhaled corticosteroids.

ADVAIR® should not be used to treat acute symptoms of asthma or COPD. It is crucial to inform patients of this. For asthma, a rapid onset, short duration β_2 -agonist should be prescribed for this purpose. Medical attention should be sought if patients find that rapid onset, short duration relief bronchodilator treatment becomes less effective or if they need more inhalations than usual. Sudden worsening of symptoms may require increased corticosteroid dosage, which should be administered under medical supervision. As twice-daily regular treatment, ADVAIR® provides twenty-four hour bronchodilation and can replace

regular use of a rapid onset, short duration (4 hour) inhaled or oral bronchodilator (e.g. salbutamol). Rapid onset, short duration β_2 -agonists should be used only to relieve acute symptoms of asthma. Patients should be regularly reassessed so that the strength of ADVAIR® they are receiving remains optimal and is only changed on medical advice. The dose should be titrated to the lowest dose of fluticasone propionate at which effective control of symptoms is maintained.

There is no need to adjust the dose in the otherwise healthy elderly or in patients with impaired renal function. Because salmeterol is predominantly cleared by hepatic metabolism, patients with hepatic disease should be closely monitored.

Recommended Dose and Dose Adjustment

ADVAIR® DISKUS®:	Asthma		COPD	
	Children 4-11 years of age	Adults and adolescents ≥12 years of age	Adults ≥18 years of age	
ADVAIR® 100 DISKUS®	One inhalation twice daily	One inhalation twice daily	—	OR
ADVAIR® 250 DISKUS®	—	One inhalation twice daily	One inhalation twice daily	OR
ADVAIR® 500 DISKUS®	—	One inhalation twice daily	One inhalation twice daily	

ADVAIR® Inhalation Aerosol:	Asthma	
	Adults and adolescents ≥12 years of age	
ADVAIR® 125	Two inhalations twice daily	OR
ADVAIR® 250	Two inhalations twice daily	

It is intended that each prescribed dose of ADVAIR® Inhalation Aerosol be given by a minimum of two inhalations twice daily. However, the prescribed dose of ADVAIR® DISKUS® may be given by a single inhalation twice daily.

Use with Spacer Devices: Spacer devices may be used in patients who have difficulty coordinating the actuation of a metered dose inhaler (MDI) with inhalation. The dosage of ADVAIR® inhalation aerosol should be adjusted according to individual response. For patients whose asthma has been stabilized without the use of a spacer device, continuation of therapy with a spacer may require a dosage adjustment.

Two small single dose pharmacokinetic studies were conducted in subjects with asthma to investigate the performance of various spacer devices. The studies showed that following the administration of ADVAIR® inhalation aerosol, the exposure to both fluticasone propionate (FP) and salmeterol xinafoate (SAL) was significantly higher (up to 4 fold) when used with the AeroChamber Max spacer, compared to the MDI alone. Exposure to FP and SAL was also increased with the use of the AeroChamber Plus and Ventahaler spacers, but to a lesser degree than that seen with the AeroChamber Max spacer. The long term safety and clinical effect of using a spacer device with ADVAIR® inhalation aerosol was not evaluated in these studies.

Missed Dose: If a single dose is missed, instruct the patient to take the next dose when it is due.

Administration: ADVAIR® is to be administered by oral inhalation only.

The patient should be made aware that for optimum benefit ADVAIR® should be taken regularly, even when asymptomatic.

As a general rule, rinsing the mouth and gargling with water after each inhalation can help in preventing the occurrence of candidiasis. Cleansing dentures has the same effect.

SUPPLEMENTAL PRODUCT INFORMATION

Adverse Reactions

Asthma:

Table 1: Number (and percentage) of patients with drug-related adverse events (incidence $\geq 1\%$) (Safety Population)

Adverse events	Salmeterol xinafoate/ fluticasone propionate combination product	Salmeterol xinafoate and Fluticasone propionate concurrent therapy	Fluticasone propionate alone	Salmeterol xinafoate alone	Placebo
Number of patients	644	486	339	180	175
Any event	110 (17%)	81 (17%)	50 (15%)	9 (5%)	5 (3%)
Hoarseness/dysphonia	15 (2%)	11 (2%)	8 (2%)	1 (<1%)	0
Throat irritation	14 (2%)	10 (2%)	8 (2%)	1 (<1%)	1 (<1%)
Candidiasis of mouth and throat	15 (2%)	9 (2%)	5 (1%)	0	0
Headaches	16 (2%)	11 (2%)	3 (<1%)	0	0
Asthma ^a	9 (1%)	11 (2%)	3 (<1%)	0	0
Palpitations	7 (1%)	4 (<1%)	2 (<1%)	1 (<1%)	0
Cough	6 (<1%)	2 (<1%)	5 (1%)	1 (<1%)	0
Breathing disorders	6 (<1%)	2 (<1%)	4 (1%)	0	0
Candidiasis- unspecified site	6 (<1%)	3 (<1%)	4 (1%)	0	2 (1%)
Upper respiratory tract infection	5 (<1%)	5 (1%)	2 (<1%)	0	0

^a In any integrated treatment group; ^b asthma was not recorded as an adverse event in those studies which included treatment with salmeterol xinafoate alone or placebo (unless it was a serious adverse event)

Table 2: Number (and percentage) of patients with drug-related adverse events (incidence ≥ 1%) (Safety Population)

Adverse events	Salmeterol xinafoate/ fluticasone propionate MDI combination product	Fluticasone propionate alone	Salmeterol xinafoate alone	Placebo
Number of patients	622	614	274	176
Any event	67 (11 %)	71 (11 %)	29 (11 %)	9 (5 %)
Hoarseness/dysphonia	13 (2 %)	7 (1 %)	3 (2 %)	0 (0 %)
Throat irritation	13 (2 %)	14 (2 %)	10 (4 %)	3 (2 %)
Candidiasis of mouth and throat	8 (1 %)	8 (1 %)	0 (0 %)	1 (<1 %)
Headaches	11 (2 %)	11 (2 %)	5 (2 %)	3 (2 %)
Cough	3 (<1 %)	3 (<1 %)	6 (2 %)	1 (<1 %)
Hyposialivation	6 (1 %)	2 (<1 %)	1 (<1 %)	0 (0 %)

¹ in any integrated treatment group; MDI = metered dose inhaler

COPD:

Table 3: Overall adverse experiences with ≥ 3% incidence in controlled clinical trials with ADVAIR® DISKUS® in patients with COPD

Adverse Event	ADVAIR® DISKUS® 50/500 mcg (n = 169) %	ADVAIR® DISKUS® 50/250 mcg (n = 178) %	Fluticasone propionate 500 mcg (n = 391) %	Fluticasone propionate 250 mcg (n = 399) %	Salmeterol 50 mcg (n = 341) %	Placebo (n = 576) %
Any event	78	70	80	74	68	69
Ear, nose, and throat						
Upper respiratory tract infection	17	12	18	16	11	15
Nasal congestion/ blockage	4	3	7	4	4	3
Throat irritation	11	8	9	9	7	6
Upper respiratory inflammation	9	2	7	5	5	5
Sinusitis	3	3	3	6	4	2
Sinusitis/sinus infection	4	2	2	2	1	2
Hoarseness/dysphonia	3	5	5	5	<1	1
Candidiasis mouth/ throat	7	10	12	6	2	<1
Lower respiratory						
Viral respiratory infections	8	6	9	5	5	4
Neurology						
Dizziness	3	4	2	2	4	2
Headaches	18	16	17	13	14	11
Gastrointestinal						
Nausea & vomiting	4	2	4	4	3	3
Non-site specific						
Fever	4	4	3	3	1	3
Musculoskeletal						
Malaise & fatigue	4	3	3	3	2	3
Muscle cramps & spasms	8	3	2	2	3	1
Muscle pain	4	0	3	2	1	<1
Musculoskeletal pain	12	9	9	10	12	10

OVERDOSAGE

ADVAIR® should not be used more frequently than twice daily (morning and evening) at the recommended dose. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Large doses of inhaled or oral salmeterol (12 to 20 times the recommended dose) have been associated with clinically significant prolongation of the QTc interval, which has the potential for producing ventricular arrhythmias.

There are no data available from clinical trials on overdose with ADVAIR®, however data on overdose with individual drugs is given below. The expected signs and symptoms of salmeterol overdosage are those typical of excessive beta2-adrenergic stimulation, including tremor, headache, tachycardia, increases in systolic blood pressure, cardiac arrhythmias, hypokalemia, hypertension and, in extreme cases, sudden death. Treatment should be symptomatic; cardiac and respiratory function should be monitored and support provided if necessary. The preferred antidote is the judicious use of a cardioselective beta-blocking agent. Cardioselective beta-blocking drugs should be used with caution, bearing in mind the danger of inducing an asthmatic attack. Serum potassium level should be monitored. If ADVAIR® therapy has to be withdrawn due to overdose of the beta-agonist component of the drug, provision of appropriate replacement steroid therapy should be considered.

Acute inhalation of fluticasone propionate doses in excess of those approved may lead to temporary suppression of the hypothalamic-pituitary-adrenal axis. This does not usually require emergency action, as normal adrenal function typically recovers within a few days.

If higher than approved doses are continued over prolonged periods, significant adrenocortical suppression is possible. There have been very rare reports of acute adrenal crisis occurring in children exposed to higher than approved dosages (typically 1000 mcg daily and above), over prolonged periods (several months or years); observed features included hypoglycemia and sequelae of decreased consciousness and/or convulsions. Situations which would potentially trigger acute adrenal crisis include exposure to trauma, surgery or infection or any rapid reduction in dosage. Patients receiving higher than approved dosages should be managed closely and the dose reduced gradually.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

The full Product Monograph is available at <http://www.gsk.ca> or by contacting:

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7333 Mississauga Road
Mississauga, Ontario L5N 6L4
1-800-387-7374

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MEDRURALE

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Donner votre nom au complet et votre adresse de courriel. Si vous ajoutez aussi une courte biographie, elle pourra être affichée sur la liste en guise de présentation. Vous pouvez aussi accéder aux archives de MedRurale et à un formulaire d'inscription au serveur de liste anglophone sur la page d'accueil du site de la SCMR, srpc.ca.

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