

PREVALENCE OF PRESSURE ULCERS IN CANADIAN HEALTHCARE SETTINGS

– M. Gail Woodbury, BScPT, MSc, PhD; and Pamela E. Houghton, PhD, BScPT

Although statistics regarding the number of pressure ulcers in the US and other countries are available, little information is known about the number of individuals in Canada who have pressure ulcers. Such information is important to assess the scope and healthcare costs of pressure ulcers and develop public policies. To obtain estimated pressure ulcer prevalence rates in Canada, existing data (gathered between 1990 and 2003) from different healthcare settings across the country were obtained from peer-reviewed published studies and from unpublished studies provided by individuals and pressure ulcer support surface manufacturers. Methods used to gather and report prevalence data in each study were critically appraised using a modified version of published criteria. Retrospective chart audit studies that did not involve direct patient assessment were excluded. The data included information from 18 acute care facilities involving 4,831 patients, 23 non-acute care facilities with 3,390 patients, 19 mixed healthcare settings with 4,200 patients, and five community care agencies that surveyed 1,681 patients. Estimates of pressure ulcer prevalence were 25.1% (95% Confidence Interval, 23.8% to 26.3%) for acute care settings, 29.9% (95% Confidence Interval, 28.3% to 31.4%) in non-acute care settings, 22.1% (95% Confidence Interval, 20.9% to 23.4%) in mixed health settings, and 15.1% (95% Confidence Interval, 13.4% to 16.8%) in community care. The overall estimate of the prevalence of pressure ulcers in all healthcare institutions

across Canada was 26.0% (95% Confidence Interval, 25.2% to 26.8%). The Canadian prevalence estimates differed among the healthcare settings and were higher than those reported in the US and the Netherlands. Although additional studies are needed, the data suggest that pressure ulcers are a significant concern in all healthcare settings in Canada.

KEYWORDS: pressure ulcers, epidemiology, prevalence, Canada, healthcare settings

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Clinicians working in wound care appreciate how life for individuals with wounds is disrupted by care, cost issues, and the pain associated with treatment. Although managing pressure ulcers is often a passion for wound care specialists, the majority of the population is unaware of the challenges involved and many healthcare professionals place little emphasis on identifying and treating skin ulcers. The number of individuals seeking wound care services continues to grow, which suggests that pressure ulcers are a relatively common healthcare concern and an escalating problem. Statistics are available regarding the number of pressure ulcers in the US¹ as well as for other countries of the world.² However, little information is available

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about the number of individuals in Canada who have pressure ulcers. National estimates for the number of pressure ulcers in various healthcare settings in regions across Canada are nonexistent. Without this information, estimating costs to the Canadian healthcare system associated with managing chronic wounds is not possible.

Pressure ulcers are not nationally recognized as an important healthcare problem in Canada. Currently, little national or provincial funding is available to provide coordinated healthcare delivery programs for their prevention and management or to promote the development of educational programs for healthcare professionals. Furthermore, nationally funded grants to support research programs for identifying the underlying cause of chronic wounds and establishing new interventions and innovative healthcare delivery models are rare. To focus national attention and resources on this serious and growing healthcare problem in Canada, national awareness about pressure ulcers must be raised. Gathering facts and statistical data that describe the extent of the problem in Canada is essential to the success of lobbying healthcare administrators and government officials and for informing the general Canadian population about the extent of the problem.

Recently, the National Pressure Ulcer Advisory Panel (NPUAP) completed a large study describing the prevalence of pressure ulcers in the US.³ In Canada, many national organizations that support other common disease conditions such as diabetes, cardiovascular disease, and cancer have invested significant human and financial resources to develop and maintain large national registries. Clearly, gathering this information is no small task. It takes years to organize, collect, and collate the data.

Given the enormity of the task, the authors believed an important first step was to systematically search and identify existing data on the prevalence of pressure ulcers in Canada. Specifically, the goal of this project was to determine, from current available information, the prevalence of pressure ulcers in different care settings

in regions across Canada. Prevalence refers to the proportion of a group (patients not ulcers) that has a pressure ulcer at a given single point in time or time period during which the cases are counted. A cross-sectional study is the appropriate design for determining the number of patients with pressure ulcers from the number of patients assessed.

Methods

Data collection. Between January 2003 and November 2003, all available data from prevalence studies conducted between 1990 and 2003 were collected. Several sources for locating studies on the prevalence of pressure ulcers in all healthcare settings and in the general population were investigated, including peer-reviewed published reports, unpublished studies, and wound care company databases. For studies in which prevalence could be separated by facility or facility type, each facility or facility type was treated as a distinct study.

Systematic computer and manual searches of library databases PubMed (Medline®) and CINAHL® were conducted using the keywords *ulcers*, *Canada*, and *prevalence* to locate studies involving all healthcare settings and populations published in peer-reviewed journals. Few published articles describing the prevalence of pressure ulcers in Canada were found. After locating the articles, all references were reviewed and researchers in this field were contacted

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KEY POINTS

- The problem of pressure ulcers spans the continuum of healthcare settings and affects a wide variety of healthcare professionals.
- To obtain nationwide pressure ulcer prevalence estimates, the authors obtained published and unpublished prevalence data obtained in Canada between 1990 and 2003 using actual skin assessments.
- The overall prevalence rate was high (26%) with higher rates (29%) in non-acute and lower rates (15%) in community care settings.
- The differences between these findings and those reported from other countries warrant further examination because they may be the result of study methodology or patient/care differences.

TABLE 1 QUESTIONS FOR CRITICALLY APPRAISING STUDIES OF PREVALENCE OF PRESSURE ULCERS IN A HEALTH SETTING

A. Are the study methods valid?

1. Is the sample random or the whole population surveyed?
2. Is the study design prospective? Is a physical examination performed?
3. Is the sample size adequate (>300 subjects)?
4. Are objective, suitable, standard methods used for measurement of pressure ulcers?
5. Is the outcome measured in an unbiased fashion?
6. Is the response rate adequate? Are the refusers described?

B. What is the interpretation of the results?

7. Are the estimates of prevalence given with confidence intervals?
8. Are the estimates of prevalence given in detail by subgroups?

C. What is the applicability of the results?

9. Are the study subjects and the setting described in detail and similar to those of interest to you?

Each question is scored 0 (no) or 1 (yes) to yield a Methodological Score ranging from 0-9.

term *mixed health settings* refers to prevalence studies in settings that consist of a mixture of acute, non-acute and/or community care healthcare delivery models; the prevalence estimate is expressed overall rather than broken down by specific setting type.

The methodology used to collect prevalence information in all studies, published and unpublished, was critically appraised using a modified version of recommended criteria for evaluating

to locate peer-reviewed articles that might have been missed.

Many members of the Canadian Association for Wound Care (CAWC) responded to a general website request for information and provided unpublished Canadian study data. Approximately 50 people were contacted; often, the search for studies required contact with several people before the correct contact was made.

Several wound care companies have large databases of prevalence and/or incidence studies performed as a service for their customers. One company, Kinetic Concepts, Inc. (KCI Medical Canada, Inc., Mississauga, Ontario) expended great effort to contact individual consumers to address proprietary and confidentiality issues in order to share this valuable information. The results of individual studies conducted in Ontario and Quebec were made available. In addition, aggregate data (without facility names and without patient information) were provided by KCI and Hill-Rom Canada (Mississauga, Ontario).

Definitions and critical appraisal. Because of regional differences and recent changes in terminology, the term *non-acute care* has been used in this report to include the following types of care setting: subacute care, chronic care, complex continuing care, long-term care (LTC), and nursing home. The

ating prevalence studies.⁴ The original critical appraisal work by Loney et al⁴ relates to patients with dementia and consists of a series of questions that are more appropriate for health problems that can be evaluated using population surveys than for chronic wounds, which are generally evaluated in healthcare facility settings. Hence, it was necessary to modify the questions to reflect the most common study situations in which patients in healthcare facilities were evaluated, often by physical examination over a relatively short time. The critical appraisal questions used in the present report are listed in Table 1.

The authors independently determined a methodological score for each study by assigning each of the nine numbered questions a score of one (1) point if appropriate methods were used. The final methodological score for each study was obtained by consensus, with higher score studies representing more appropriate and rigorous research methods and less potential bias in the results. Therefore, prevalence estimates from studies with higher methodological scores can be accepted with more confidence.

Questions 2, 4, and 5 of the critical appraisal (see Table 1) were the most vital. Studies were considered to lack validity if: 1) responses indicated that skin ulcers were counted by methods other than direct physical skin assessment, 2) outcome measures used

TABLE 2
OUTLINE OF THE RECEIVED STUDIES

	Acute care	Non-acute care	Community care	Mixed health
Number of studies received	12	23	4	6
Number of facilities	18	23	5	19
Total number of patients	4,831	3,390	1,681	4,200
Years studies conducted	1990-2002	1990-2003	1990-2003	1990-2003
Sample size:				
Mean	439	206	420	700
Minimum - maximum	58-1,525	65-768	29-1,466	202-2,384
Methodological score 0-9				
Mean	6.3	6.5	5.6	6.6
Range	2 to 8	2 to 7	3.5 to 6.5	6 to 7
Number of excluded studies (Score <2, or negative response to questions 2, 4, and 5)	1	5	0	0

non-acute care were received. Across 65 healthcare facilities/institutions, 14,102 patients were evaluated in prevalence studies, demonstrating a wide range of sample sizes (between 29 and 2,384). No studies of pressure ulcers prevalence in

to identify pressure ulcers were not those accepted as the standard, and 3) the presence of ulcers was determined by healthcare professionals responsible for patient care rather than by unbiased assessors. Studies for which the responses to all three questions were negative and studies with scores <2 were excluded from the summary statistics generated for this report. The relationship between prevalence and methodological score was investigated to ascertain the extent to which control of bias might affect prevalence estimates.

Statistical analyses. The published and unpublished studies included were summarized within the relevant healthcare setting. The point estimate of prevalence is expressed as a percentage of the total population at risk. Construction of the 95% Confidence Interval (CI) around the estimate allows that the authors are 95% confident the true prevalence is between the confidence limits. The formula for the 95% CI has been published previously.⁵

Results

Data received. The number of individual published and unpublished studies obtained for four healthcare settings (acute care, non-acute care, community care, and mixed healthcare) for the years 1990 to 2003 is shown in Table 2. As few as four studies for community care and as many as 23 for

the general population were found.

In addition to individual studies, aggregated information about numerous individual studies was received from two wound care companies. The estimates were based on aggregate data and have not been combined with individual studies because information about facility type, location, and patient population was insufficient. Nevertheless, because the methods used by each company are consistent within the company and are of high quality, the prevalence estimates are reported.

Published studies. Literature searches yielded seven prevalence studies conducted in Canadian healthcare institutions. An eighth article, published in 1994 but conducted before 1990, was excluded.⁶ Information about each of these studies, including the assigned methodological score, is shown in Table 3.

The earliest study of pressure ulcers in this time period, reported by Foster,⁷ was conducted in three tertiary care hospitals, one community hospital, two LTC facilities, and two community agencies in Ontario. Overall pressure ulcer prevalence for all health facilities was 25.7%⁷; separate prevalence estimates for acute care, extended care, and community agencies were gathered from a figure in the original article.

Two prevalence studies conducted in acute care facilities achieved high methodological scores using an appropriate cross-sectional study design and careful

TABLE 3
PUBLISHED CANADIAN STUDIES

References	Subjects	Design/method	Facility type	Prevalence	Data source	Method score
Foster et al, 1992 ⁷	N=2,384 from three teaching hospitals, one community hospital, two long-term care facilities, two community health agencies in Ontario	Patients assessed over 1 day, one skin care committee nurse/unit as surveyor; surveyors trained	Overall Acute care Extended care Community agencies	25.7 27 30 13	Clinical	6.5
Harrison et al, 1996 ⁸	N=738 from acute care 740-bed facility in Ontario	Patients assessed within 12-hour period (skin breakdown, risk); conducted midweek to reflect accurate mix of admissions and case types, in September to avoid seasonal fluctuations. Education workshop; survey team trained, validated; 10% reliability checked	Acute care	29.7 (95% CI 26.4-33.0)	Clinical	8
Fisher et al, 1996 ⁹	N=1,020 from two acute care hospitals in Ontario	Patients assessed within 12-hour period (skin breakdown, risk) by survey teams of RNs. Study conducted midweek to reflect mix of new admissions and long stay operative cases. ET therapists available for difficult to classify ulcers	Acute care	23.9	Clinical	8
McNaughton & Brazil, 1995 ¹⁰	N=210 and 202 from one facility in Ontario	Pre and post intervention. 2-week period prevalence: Survey of all patients by nurses to locate ulcers; ulcer physical assessment using standard form	Chronic care	Year 1:32.4 Year 2: 22.3	Clinical	5
Nicolle et al, 1994 ¹²	N= 198 and 259 from two long-term care facilities in Ontario	Prospective surveillance for 2-year period. Patients with decubiti identified at the beginning of the study period; surveillance and data collection including microbiological studies by study nurse who visited the facility at least twice per week. Residents with ulcers followed until ulcer healed, discharge, or death, or participation termination	Long-term care	2.8 and 3.5	Clinical	2
D'hoore et al, 1997 ¹³	N=13,555 from long-term care facilities in Quebec, except psychiatric or totally private centers	Retrospective analysis of administrative data set for year 1993-1994. "Required nursing time measurement tool" identified nursing actions required. Pressure ulcer existence inferred from evaluation of required nursing actions, treatment of pressure sores; distinction between Stage I and Stage II versus Stage II and Stage IV	Long-term care	4.0	Database	2
Davis & Caseby, 2001 ¹¹	N= 95 and 92 from two long-term care facilities in Ontario	Patients assessed by KCI member, one facility nurse, one healthcare aide/team, on 1 day, standard procedures for presence and number of ulcers	Long-term care	36.8 and 53.2	Clinical	7

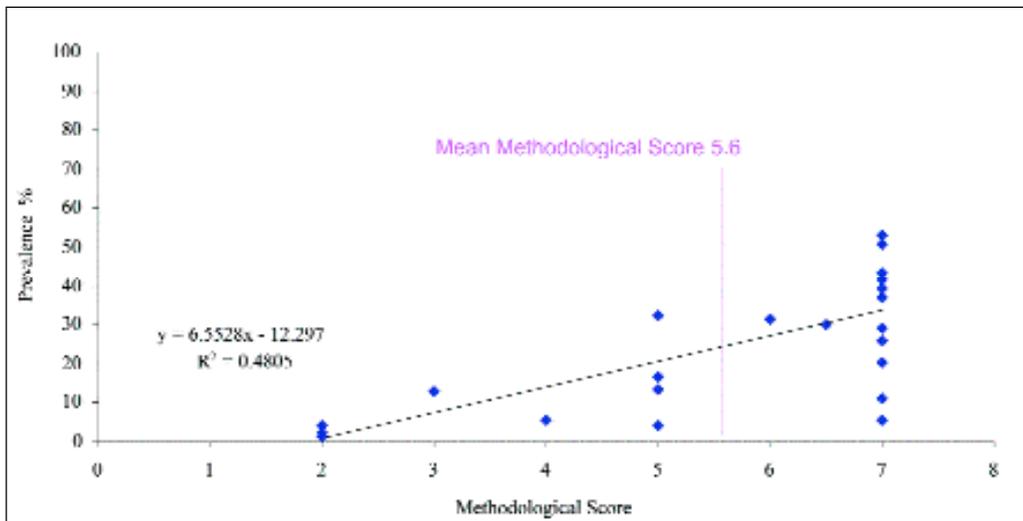


Figure 1
Prevalence by methodological score in non-acute care.

methods (eg, standard definitions of pressure ulcer presence and staging) to ensure that assessments were done reliably and without bias.^{8,9} These two studies produced prevalence estimates of 29.7% and 23.9%, respectively.

The only Canadian study estimating the prevalence of pressure ulcers in a chronic care facility in Ontario was conducted before 1995, with pre and post wound care protocol evaluations.¹⁰ The study's methodological score of 5 was affected by the relatively small sample size and by the fact that patients with ulcers were identified based on patient survey responses obtained by the nurses before direct physical examination.

The study of pressure ulcers in LTC with the highest methodological score (7) produced high estimates of prevalence — 36.8% and 56.2%.¹¹ A lower estimate was obtained in another LTC study in which ulcers were assessed using non-standard measures.¹² A third study in LTC, which was not conducted primarily to determine prevalence, created an unfavorable

situation. Specifically, the Quebec LTC database was analyzed retrospectively to determine the relationship between presence of pressure sores and nursing workload.¹³ The use of a retrospective analysis rather than a cross-sectional study design provided an imperfect situation for determining prevalence because

specific data on the presence of pressure ulcers were not recorded. The presence of pressure ulcers was inferred from an evaluation of required nursing actions for the treatment of pressure ulcers. The retrospective study design and nonstandard measurement of outcome adversely affected the methodological score obtained in the critical appraisal. These two latter studies had poor methodology scores and were excluded from the summary data.

Unpublished studies. Thirty-three unpublished studies were received from 19 people. Of these, 30

TABLE 4
PREVALENCE ESTIMATE: ACUTE CARE*

Study	Year	Sample size	Methodologic score 0-9	Prevalence	Prevalence
Ontario 1a	1990	1,525	6.5	27	
Ontario 2	1993	738	8	29.7	13.6
Ontario 3	1994	1,020	8	23.9	
Nova Scotia 1	1995	233	5	26.2	9.4
British Columbia 1a	1997	58	5	15.5	
Newfoundland 1	2002	203	5	4.9	
Ontario 4	1998	135	6	26.7	17.0
British Columbia 2	2000	250	5	34.8	
KCI 4	2002	133	7	18.8	
KCI 5	2000	112	7	34.8	
KCI 11	2002	424	7	16.3	

*Sample size, methodological score, and prevalence estimates of individual published, unpublished and KCI clinical studies
These studies were numbered within each province; letters were applied to studies represented in different settings.

were accepted for use in this report. Included with the unpublished studies were 11 individual studies provided by a company — three representing acute care and eight representing non-acute care. All unpublished studies were critically evaluated and the results combined with the published studies.

After excluding the studies with scores of 2 or less and those with negative answers to the three key methodological questions, the mean methodological scores for the published and unpublished studies across the four healthcare settings ranged from 5.6 to 6.6 (maximum = 9) (see Table 2).

Prevalence estimates.

Estimates of prevalence from studies with poorer methodological scores tended to be lower than estimates obtained from studies in which bias was controlled (see Figure 1). Therefore, studies with scores ≤ 2 were excluded.

The prevalence estimates of the individual published, unpublished, and KCI studies were summarized for acute

care, non-acute care, community, and mixed health settings (see Tables 4 to 7, respectively). The overall mean prevalence for the healthcare settings ranged from 15.1% (95% CI, 13.4% to 16.8%) in community care, to 29.9% (95% CI, 29.3% to 31.4%) in non-acute care, with mixed health setting at 22.1% (95% CI, 20.9% to 23.4%) and acute care at 25.1% (95%

TABLE 5
PREVALENCE ESTIMATE: NON-ACUTE CARE*

Study	Year	Sample size	Methodologic al score 0-9	Prevalenc e	Prevalenc e
Ontario 5a	2000	95	7	36.8	
Ontario 5b	2000	92	7	53.3	
Ontario 6	1993	210	5	32.4	
Ontario 1b	1990	768	6.5	30.0	
Nova Scotia 2	1995	206	6	31.6	13.1
Newfoundland 2	2002	143	5	4.2	
British Columbia 3	2000	136	5	13.2	
British Columbia 4	2000	120	5	16.7	
British Columbia 1b	1997	229	7	10.9	
British Columbia 1c	1997	143	7	5.6	
KCI 1	2002	142	7	39.4	
KCI 2	2003	65	7	29.2	
KCI 3	2002	157	7	20.4	
KCI 6	1999	92	7	53.3	
KCI 7	2001	142	7	26.1	
KCI 8	2002	180	7	43.3	
KCI 9	2001	231	7	41.6	
KCI 10	2002	239	7	51.0	

*Sample size, methodological score, and prevalence estimates of individual published, unpublished and KCI clinical studies

These studies were numbered within each province; letters were applied to studies represented in different settings.

TABLE 6
PREVALENCE ESTIMATE: COMMUNITY CARE*

Study	Year	Sample size	Methodologic al score 0-9	Prevalenc e	Prevalenc e
Ontario 1c	1990	91	6.5	13.2	
British Columbia 1d	1997	29	6	24.1	
Saskatchewan 1	2001	95	3.5	15.8	
Manitoba 1	2003	1,466	6.5	15.0	

*Sample size, methodological score, and prevalence estimates of individual published, unpublished and KCI clinical studies

These studies were numbered within each province; letters were applied to studies represented in different settings.

CI, 23.8% to 26.3%) (see Figure 2). The 95% confidence limits for each estimate were narrow (less than two percentage points from the estimate), reflecting the large sample sizes that resulted from the combination of studies. Conversely, a large range of values was noted between the minimum and maximum estimates reported for the pressure ulcer prevalence

**TABLE 7
PREVALENCE ESTIMATE: MIXED HEALTH SETTINGS***

Study	Year	Sample size	Methodologic al score 0-9	Prevalenc e	Prevalenc e
Ontario 1d	1990	2384	6.5	25.7	11.0
Ontario 7	2001	406	7	13.1	9.4
Ontario 8	1998	310	7	21.6	13.5
British Columbia 5	1996	202	6	10.9	-
Nova Scotia 3	1995	439	6	28.7	11.2
British Columbia 1e	1997	459	6	10.7	6.7

*Sample size, methodological score and prevalence estimates of individual published, unpublished and KCI clinical studies
These studies were numbered within each province; letters were applied to studies represented in different settings.

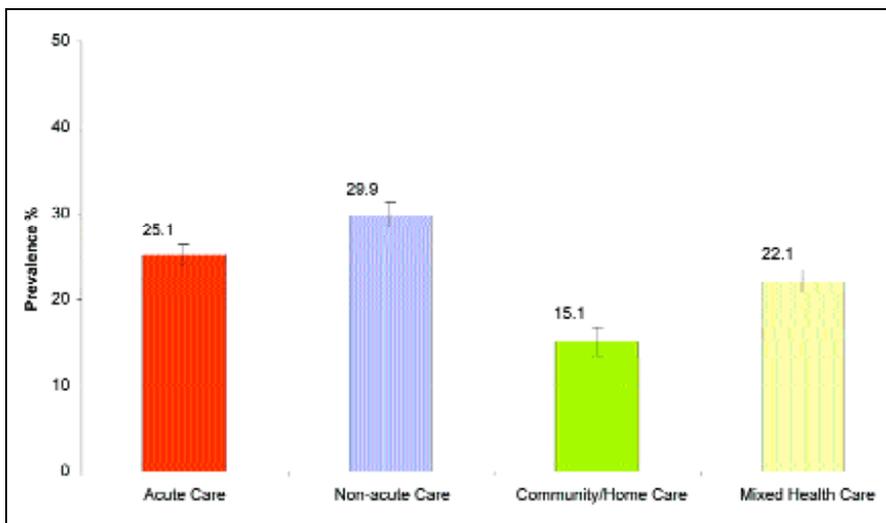


Figure 2
Estimates of pressure ulcer prevalence in various healthcare settings (95% Confidence Interval bars).

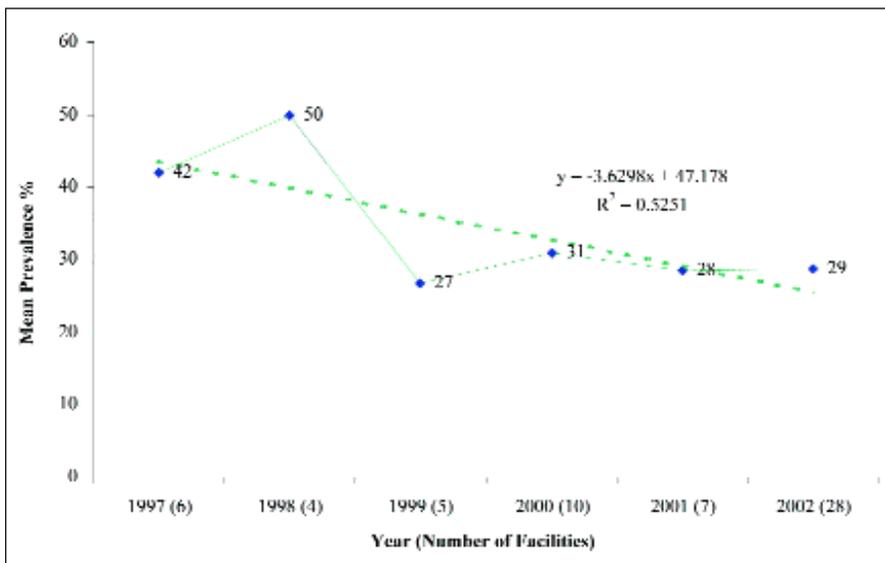


Figure 3
Acute care prevalence: KCI Studies 1997-2002.

of each individual study. Because the confidence limits for different health-care settings do not overlap, the estimates in these settings are significantly different. When all data are combined to report overall prevalence (regardless of setting and avoiding representing study data more than once), the mean prevalence is higher at 26% (95% CI, 25.2-

26.8%), based on 10,911 subjects.

Aggregate data prevalence estimates. KCI provided yearly prevalence estimates for 61 acute care facilities from studies conducted from 1997 to 2003. Because similar research methods were used to collect these prevalence estimates, they can be compared over time (see Figure 3). Estimates of pressure ulcer prevalence were found to decrease gradually from 42% in 1997 to 29% in 2002.

Results of prevalence studies conducted by Hill-Rom in 35 acute and non-acute Canadian facilities — ie, mixed healthcare settings — from 2001 to 2003 produced a prevalence estimate of 14.9% based on 6,828 patients.

Discussion

This project provided reliable estimates of pressure ulcer prevalence for four healthcare settings in Canada. The estimates, which have narrow confidence intervals, are based on individual studies that were critically appraised and found to be methodologically sound, yielding large combined samples from across the country

Collagenase Santyl[®] Rx only

321 units/g
OINTMENT

DESCRIPTION

Collagenase Santyl[®] Ointment is a sterile enzymatic debriding ointment which contains 250 collagenase units per gram of white petrolatum USP. The enzyme collagenase is derived from the fermentation by *Clostridium histolyticum*. It possesses the unique ability to digest collagen in necrotic tissue.

CLINICAL PHARMACOLOGY

Since collagen accounts for 70% of the dry weight of skin tissue, the ability of collagenase to digest collagen in the physiological pH and temperature range makes it particularly effective in the removal of debris.¹ Collagenase thus contributes towards the formation of granulation tissue and subsequent epithelialization of thermal ulcers and severely burned areas.^{2, 3, 4, 5, 6} Collagen in healthy tissue or in newly formed granulation tissue is not affected.^{7, 8, 9, 10, 11, 12} There is no information available on collagenase absorption through skin or its concentration in body fluids associated with therapeutic or under toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier.

INDICATIONS AND USAGE

Collagenase Santyl Ointment is indicated for debriding chronic thermal ulcers, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and severely burned areas, 1, 4, 6, 7, 8, 9, 10, 11.

CONTRAINDICATIONS

Collagenase Santyl Ointment is contraindicated in patients who have a known local or systemic hypersensitivity to collagenase.

PRECAUTIONS

The optimal pH range of collagenase is 6 to 8. Higher or lower pH conditions will decrease the enzyme's activity and appropriate precautions should be taken. The enzymatic activity is also adversely affected by certain detergents, and heavy metal ions such as mercury and silver which are used in some antiseptics. When it is expected that metallic ions have been used, the site should be carefully debrided by repeated washings with normal saline before Collagenase Santyl Ointment is applied. Soaks containing metal ions or acidic solutions should be avoided because of the metal ion and low pH. Cleansing solutions such as hydrogen peroxide, iodoine solution, and normal saline are compatible with Collagenase Santyl Ointment.

Debrided patients should be closely monitored for systemic bacterial infections because of the theoretical possibility that debriding enzymes may increase the risk of bacteremia. A slight transient erythema has been noted occasionally in the surrounding tissue, particularly when Collagenase Santyl Ointment was not confined to the wound. Therefore, the ointment should be applied carefully within the area of the wound. Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. However, rare cases of systemic manifestations of hypersensitivity to collagenase in a patient treated for more than one year with a combination of collagenase and carboxymethyl cellulose have been reported.

OVERDOSAGE

No systemic or local reactions attributed to overdose have been observed in clinical investigations and clinical use. If deemed necessary the enzyme may be inactivated by washing the area with phosphate saline.

DOSAGE AND ADMINISTRATION

Collagenase Santyl Ointment should be applied once daily (or more frequently if the dressing becomes soaked, see Instructions). When clinically indicated, crosshatching fresh eschar with a #10 blade allows Collagenase Santyl Ointment more surface contact with necrotic debris. It is also desirable to remove, with forceps and scissors, as much loosened debris as can be done readily. Use Collagenase Santyl Ointment in the following manner:

1 - Prior to application the wound should be debrided of debris and digested material by gently rubbing with a gauze pad saturated with normal saline solution, or with the debriding cleansing agent compatible with Collagenase Santyl Ointment (See PRECAUTIONS), followed by a normal saline solution soak.

2 - Whenever infection is present, it is desirable to use an appropriate topical antibiotic powder. The antibiotic should be applied to the wound

prior to the application of Collagenase Santyl Ointment. Should the infection not respond, therapy with Collagenase Santyl Ointment should be discontinued until resolution of the infection.

3 - Collagenase Santyl Ointment may be applied directly to the wound or to a sterile gauze pad which is then applied to the wound and properly secured.

4 - Use of Collagenase Santyl Ointment should be terminated upon debridement of necrotic tissue is complete and granulation tissue is well established.

HOW SUPPLIED

Collagenase Santyl Ointment contains 250 units of collagenase enzyme per gram of white petrolatum USP. The activity assay of collagenase is based on the digestion of undenatured collagen from bovine Achilles tendon at pH 7.5 and 37°C for 24 hours. The number of peptide bonds cleaved are measured by reaction with ninhydrin. Amino groups released by a tyrosin digestion control are subtracted. One unit collagenase will oxidize ninhydrin reactive material equivalent to 4 micromoles of leucine.

Do not store above 80°C (77°F). Sterility guaranteed until tube is opened.

Collagenase Santyl Ointment is available in 15 gram and 30 gram tubes.

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for most healthcare facility types.

The prevalence estimates obtained and a desired narrow 95% CI width of 10% can be used to ascertain the sample size requirements for conducting a future prevalence study in each of the healthcare settings, using the formula suggested by Baumgarten.⁵ (The acceptance of a 95% CI wider than 10% results is a trade-off in precision for a smaller sample size requirement.) The required sample size estimates are: 289 acute care subjects, 322 non-acute care subjects, 197 community care subjects, and 265 mixed healthcare subjects. In other words, in settings in which the prevalence is anticipated to be above 25%, a approximately 300 subjects are needed, while fewer subjects are needed if the prevalence is anticipated to be as low as 15%. These sample size calculations lend support to the methodological criterion suggested by Loney et al⁴ that appropriate sample size for prevalence studies is greater than 300 subjects to allow for the possibility that the prevalence is as high as 25%.

Comparing estimates with those from other countries suggests that the estimate for the number of patients with pressure ulcers in acute care (25.1%) is higher than two previously reported pressure ulcer prevalence estimates from across the US.^{1,3} The NPUAP pressure ulcer prevalence estimate ranged between 10% and 17.1%.³ Whittington et al¹ reported a 15.1% prevalence of pressure ulcers from a series of studies conducted by KCI in acute care facilities across the US. The differences between Canadian and US estimates of prevalence of pressure ulcers in acute care facilities might be due to different methodologies employed and the time period over which the data were collected. However, US and Canadian estimates generated by KCI in 1999 using identical methods found a pressure ulcer prevalence estimate in Canada of 27% (see Figure 3) that was considerably higher than the 15.1% value reported in US.¹ Therefore, these estimates may represent true differences between the Canadian and US healthcare systems. Other possible explanations include differences in the sample sizes and patient profiles. The US KCI estimate reported by Whittington was limited to adult patients in medical-surgical and intensive care units, while samples surveyed in Canadian healthcare institutions in this report included more units.

The study prevalence estimate for patients in non-

acute care facilities in Canada (29%) is close to the upper value in the range reported by the NPUAP, 2.3% to 28%,³ and to another recently published prevalence estimate (28%).¹⁴ Horn et al¹⁴ used a retrospective cohort sample of 2,420 patients who were at risk of developing pressure ulcers as indicated by Braden scores of 17 or less. One would have expected the current estimates for pressure ulcer prevalence in all patients within Canadian non-acute care facilities to be much higher than estimates from the US that examined only patients who had already been identified as at risk of developing pressure ulcers. Differences between current estimates in Canada and US pressure ulcer prevalence estimates may be due to the use of different methodologies — the US study used retrospective analysis rather than direct skin examination from which the Canadian estimates in this report were derived. The authors found that studies that used retrospective data analysis received lower methodological scores and tended to produce lower prevalence estimates; therefore, these studies may be more likely to underestimate true prevalence of pressure ulcers.

Differences between Canadian and US estimates of pressure ulcer prevalence also may be explained by the fact that the term *non-acute care* encompasses a potentially diverse population. The descriptors for healthcare facilities with non-acute patients have changed over the past several years and are not uniform in different regions across Canada. They include LTC, nursing homes, complex continuing care, skilled nursing facilities, rehabilitation, and geriatrics. Because of the varying terminology, the results were combined into a generic category: non-acute care. It is possible that the true prevalence in any particular subgroup within this classification may be masked by this healthcare setting's diversity.

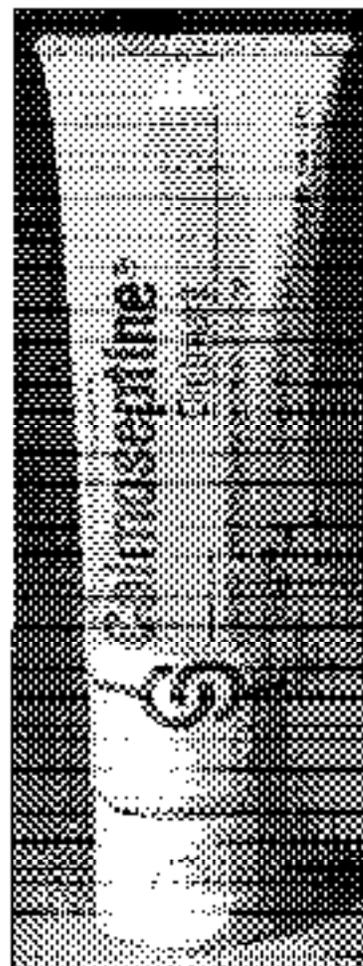
The national estimate of pressure ulcer prevalence in Canada (26%) is slightly higher than the estimate reported from a national study done in the Netherlands and considerably higher than the international aggregate estimate for 2003 provided by Hill-Rom. The epidemiological study performed in the Netherlands examined 16,344 patients and produced an overall estimate of 23.1% for all the health settings.² The international estimate from Hill-Rom was 15.5%, based on 61,427 surveyed patients in 461 facilities of all types. The majority of these Hill-Rom international studies were conducted in the US.

Limitations

The diversity of the non-acute care population that was combined for the present project may have resulted in an estimate for this generic sample that is not accurate for any of the subgroups, (eg, LTC facilities, nursing homes, complex continuing care, skilled nursing facilities, rehabilitation, and geriatrics).

Most studies, published and unpublished, reported insufficient information to answer all the methodological questions about the

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studies. Some gaps in information were filled by additional contacts with project authors but when the information was not available or authors could not be contacted, it was assumed that rigorous methods were not performed or that certain results were not obtained.

The data obtained do not represent all data collected from Canadian healthcare settings. No estimates of prevalence in acute and non-acute care came from the Prairie Provinces; therefore, one must assume that the prevalence of pressure ulcers in these two settings would be similar in these provinces. The information received is only a sample from relatively few institutions across Canada. It is possible that facilities electing to do prevalence studies do so when they suspect a potential problem and this might contribute to the higher prevalence reported in relation to other countries.

All pressure ulcer prevalence estimates obtained for this project are within the healthcare sector; no national estimate was secured for the general population. Several national databases, such as the National Population Health Survey (NPHS), were reviewed in vain to find a statistic for the population.

Conclusion

This project provides prevalence estimates for pressure ulcers in various Canadian healthcare settings of 15% to 30%, and an overall estimate of 26%. These estimates seem to be higher than estimates from the US and the Netherlands, perhaps because of the trend in the Canadian healthcare system to limit hospital admission and reduce length of stay; thereby, resulting in sicker patients within the system.

This information will be useful to clinicians, researchers, and policy makers in Canada and other countries to advocate for the needs of patients with chronic pressure ulcers. Additional information is needed about the prevalence of other types of wounds. In a recent systematic review of prevalence of lower limb ulcers, the prevalence of venous leg ulcers was determined to be 0.12% to 1.1% based on the studies that employed clinical validation of ulcers.¹⁵ More studies are needed to estimate the number people in the general population with chronic wounds of any cause. - OWM

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