An overview of the Canadian landscape on the use of restorative therapies for erectile dysfunction and Peyronie's disease

Jainik Shah[1], Maximilian G. Fidel[1], Dhiraj S. Bal[1], Armin Kharazi[2], Connor F. Roque[1], Yool Ko[1], Karim Sidhom[3], David Bouhadana[4], Francis Petrella[4], Premal Patel[3]

[1]Max Rady College of Medicine, University of Manitoba, Winnipeg, MB, Canada; [2]Men's Health Clinic Manitoba, Winnipeg, MB, Canada; [3]Section of Urology, Department of Surgery, University of Manitoba, Winnipeg, MB, Canada; [4]Division of Urology, McGill University Health Center, Montreal, QC, Canada

Cite as: Shah J, Fidel MG, Bal DS, et al. An overview of the Canadian landscape on the use of restorative therapies for erectile dysfunction and Peyronie's dsease. *Can Urol Assoc J* 2024;18(12):420-4. http://dx.doi.org/10.5489/cuaj.8804

Published online July 15, 2024

Appendix available at *cuaj.ca*

ABSTRACT

INTRODUCTION: Restorative therapies (RTs), including low-intensity shockwave therapy (Li-SWT) and platelet-rich plasma (PRP), aim to restore natural erectile function. Many clinics offer these therapies for erectile dysfunction (ED) and Peyronie's disease (PD) with direct-to-consumer (DTC) marketing. This study sought to investigate the landscape of RTs within Canadian clinics.

METHODS: Online searches were made to identify clinics offering Li-SWT and/or PRP as an RT for treating ED and PD in Canada. Public websites were analyzed, followed by calling clinics for data on cost, treatment protocols, clinic ownership, success rates, and adjunctive therapies.

RESULTS: A total of 107 clinics were identified online, with a 68.2% call response rate (n=73). Of the respondents, 56 and 40 clinics provided Li-SWT and PRP therapies, respectively, with 23 clinics offering both. All clinics reported using RTs for ED, with 21 clinics offering Li-SWT and 22 clinics providing PRP for PD. Forty-three clinics provided costs and protocols for Li-SWT, while 33 clinics did so for PRP. The average cost ± standard deviation (CAD) of six sessions of Li-SWT was $2167.24±936.11 and one shot of PRP was $1478.68±591.98. Most (60.3%, n=44) clinics reported physician ownership, with a majority (n=28) being family medicine-trained. Seven clinics did not provide data and 22 were non-physician-owned. Ten clinics provided success rates, with an average of 87.3%.

CONCLUSIONS: Despite limited data supporting their routine clinical use, many clinics across Canada offer RTs for ED and PD with varying treatment protocols and increased costs. Further research is required to evaluate the efficacy of RT for ED and PD.

INTRODUCTION

Erectile dysfunction (ED) and Peyronie's disease (PD) represent significant challenges to men's sexual health. ED, characterized by the inability to achieve or maintain an erection sufficient for sexual intercourse, affects up to 50% of men aged 40 and above.[1,2] PD manifests as the formation of fibrous plaques within the penile tissue, leading to penile curvature and pain, impacting more than 7% of men worldwide.[3-5]

While evidence-based treatment options for ED and PD, such as pharmacotherapy, intralesional therapies, and surgical treatment, are available, recent attention has turned towards novel restorative therapies (RTs), offering hope for men seeking alternatives or adjuncts to conventional approaches. RTs propose the idea of repairing or substituting damaged tissue by activating the body's natural regenerative abilities. This is an appealing option to many, as these therapies are meant to be relatively non-invasive and intend to target the underlying etiology of these conditions.

Among these emerging treatments, low-intensity extracorporeal shockwave therapy (Li-SWT) and platelet-rich plasma (PRP) injections have gained traction. Li-SWT involves the application of low-intensity sound waves to the penile tissue, stimulating microtrauma and triggering the release of growth factors, such as vascular endothelial growth factor. This process promotes vascularization, enhances blood flow to the penis, and ultimately aims to improve erectile function.[6] Meanwhile, PRP

KEY MESSAGES

- Restorative therapies, such as low-intensity shockwave therapy and platelet-rich plasma injections, are emerging restorative therapies for the treatment of ED and Peyronie's disease.
- Many clinics across Canada are offering these modalities at high prices directly to patients without complete transparency regarding their efficacy.
- Further research is required to understand the effectiveness of these therapies to better assist patients in deciding on what therapy is right for them.

therapy uses injections of platelet-rich plasma derived from the patient's blood. The high concentration of growth factors within PRP is meant to support tissue repair and regeneration, assisting both in plaque reduction and improved penile blood flow.

Studies on the efficacy of these RTs have produced mixed outcomes. While some studies have reported significant improvements in erectile function and penile curvature, others have found minimal to no benefits.[7-13] Factors such as treatment protocols, patient selection criteria, and variations in disease severity and etiology may contribute to the mixed reported success rates.

Despite the potential promise of Li-SWT and PRP therapy, concerns have been raised regarding their widespread adoption and promotion. The lack of standardized protocols, inconsistent regulation, and variable quality control associated with Li-SWT and PRP therapy pose challenges for patients and healthcare providers alike. Still, direct-to-consumer (DTC) marketing efforts have proliferated, and many clinics are providing these therapies across Canada with high costs, often not covered by insurance, placing a financial burden on patients seeking care. This marketing strategy can leave many patients without adequate guidance surrounding the efficacy of these treatment options for them, the effects of which are yet to be understood.

The primary objective of this study was to analyze the landscape of RT treatment options among Canadian clinics, gathering publicly available data and information provided by clinics upon request to understand the promotion and availability of these modalities.

METHODS

A cross-sectional study was conducted to investigate clinics offering RTs for the treatment of ED and PD throughout Canada, particularly Li-SWT and PRP injections.

Study population and data collection

Between May and September of 2023, Google™ searches were made on a private internet browser. Amalgamated search terms for Li-SWT included "Shockwave therapy for erectile dysfunction in (province/territory)," "SWT therapy for erectile dysfunction in (province/territory)," "Shockwave therapy for Peyronie's disease in (province/territory)," and SWT for Peyronie's disease in (province/territory)." Similarly, search terms for PRP included "PRP therapy for erectile dysfunction in (province/territory)," "P-shot therapy for erectile dysfunction in (province/territory)," "PRP therapy for Peyronie's disease in (province/territory)," and "P-shot therapy for Peyronie's disease in (province/territory)."

Preliminary data was collected by reviewing the publicly available information on the websites of clinics listed on the first five pages of Google search results. Clinics were organized by province, and their respective contact information was recorded in a Microsoft Excel file (Microsoft Office, Microsoft Corporation, Redmond, WA, U.S.). Clinics that outsourced their therapy to other clinics were removed, as well as those lacking a telephone number. Data was collected on cost, indication for treatment, availability of a treatment protocol, equipment used, ownership of clinics, training of treatment providers, and adjunctive therapies used.

Clinics were subsequently contacted by telephone using a standardized script to inquire about treatment details not found on their websites (Appendix available at *cuaj.ca*). If clinics did not respond, they were called again at different times during business hours for up to three attempts before being excluded from the analysis. Data was analyzed using descriptive statistics and reported using raw percentages and means with standard deviation (SD) where applicable.

RESULTS

Initially, a total of 107 clinics across Canada were identified as offering RTs for treatment indications related to ED and PD. The clinics, organized by province, are displayed in Figure 1. Of these 107 clinics, only 13.1% (n=14) provided upfront costs for either Li-SWT or PRP treatments; 5.6% (n=6) provided transparent data on their website about their success rates for Li-SWT, while only one clinic reported success rates for PRP. Most (69.2%, n=74) listed ownership data on their website.

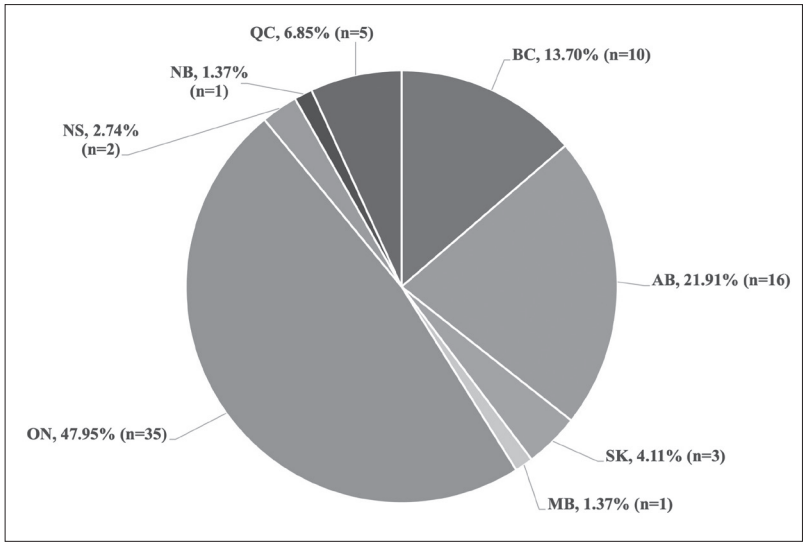

Figure 1. Clinics responses by province.

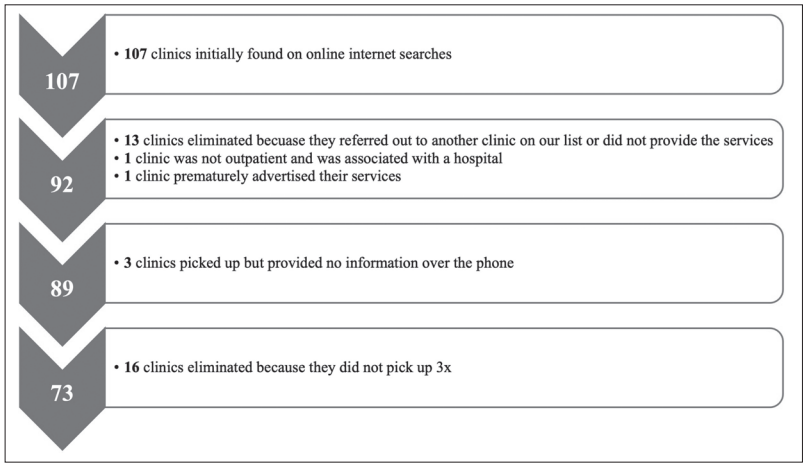

Figure 2. Study flowchart for clinic inclusion.

To address gaps in data, clinics were contacted by phone, with an achieved response rate of 68.2% (n=73). Many clinics were eliminated from statistical analysis due to reasons outlined in Figure 2. This included clinics whose websites advertised services that they could not confirm over the phone and clinics that operated in connection with a hospital and did not accept outpatients. An additional 15 clinics were not reachable over the phone, which left 73 clinics for which responses were collected. The remaining statistics are of those 73 clinics whose responses the research team was able to confirm.

Of the clinics surveyed, 76.7% (n=56) offered Li-SWT, 54.8% (n=40) provided PRP, and 31.5% (n=23) offered both RTs. All clinics reported using both modalities for ED, while 30.9% (n=21) and 32.4% (n=22) of clinics offered Li-SWT and PRP treatments for PD, respectively. Transparent costs and protocols were provided by 58.9% (n=43) and 46.6% (n=34) of the clinics for Li-SWT and PRP, respectively. On average, Canadian clinics reported the cost ± SD (CAD) for six sessions of Li-SWT as $2167.24±936.11, ranging from $700–4000. Meanwhile, the average cost ± SD (CAD) for a single PRP treatment was $1478.68±591.98, with costs ranging from $466–3000.

Although six sessions of Li-SWT and one shot of PRP is reported standard for pricing, actual protocol varied heavily among all clinics and was not formally assessed. Most (89.0%, n=65) of the clinics surveyed provided data on ownership or provider training (Figure 3). Furthermore, non-physician ownership included naturopaths, nurse practitioners, physician assistants, and physiotherapists.

Just over half (54.8%, n=40) of clinics demonstrated some form of transparency regarding RT treatment efficacy, with 10 clinics offering success rates from 60–100%, and the remaining 30 clinics providing only anecdotal evidence to support their claims. Among the clinics that opted for adjuvant therapy (n=19), the preferred choice was a vacuum erection device (VED), which was included in their pricing. One clinic recommended a VED but did not disclose its cost at the time of the call. One clinic indicated that their adjuvant therapy involved prescribing in-house exercise and physical therapy programs.

DISCUSSION

The rising popularity of RTs, as evidenced by a 782% surge in internet searches throughout the last few years, highlights a pressing need for transparency and expert urologic guidance.[14] The objective of this study was to meet this need by exploring the landscape of RTs being marketed DTC across the country. As public interest continues to grow, there is greater opportunity for predatory marketing regarding the efficacy of these therapies and the optimal conditions in which these therapies, if beneficial, may work. With increases in the prevalence of ED reaching up to 80% and PD greater than 7% in certain populations, there is a concerning trend of these conditions being exploited for commercial gain through inappropriate advertising..[4,5,15-17]

Previous studies have shown that increased marketing of men's health procedures correlates with higher rates of procedure initiation and uptake.[18] Ultimately, the decision to administer a certain treatment remains in the hands of the practitioner, with patient demand for the treatment largely influencing the decision-mak-

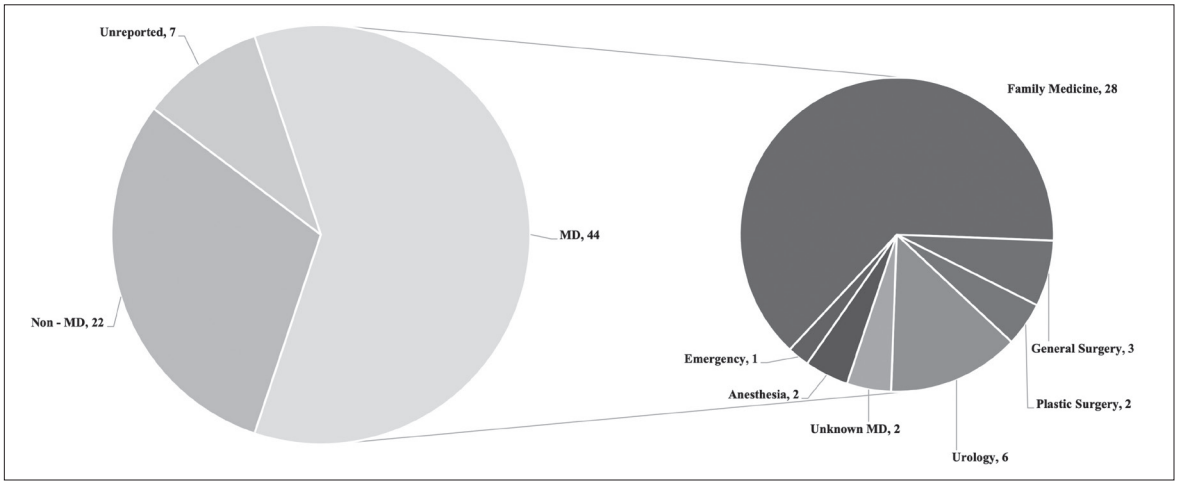

Figure 3. Clinic distribution by ownership/treatment providers.

ing process.[19] As more clinics adopt these treatments, demand will increase, despite evidence suggesting RT therapies may not be beneficial for all. Our study found that most clinics lacked any data on success rates, with less than a dozen clinics able to quantify it. Many patients, without this data, may not be able to critically evaluate if they want to seek these treatments.

At present, there exists a shortage of randomized controlled trials (RCTs) evaluating the evidence for the use of RTs in ED and PD. Existing RCTs often vary significantly in their treatment protocols, including differences in the number of sessions, types of devices used, quantity of shocks delivered, and intervals between treatments.[6,8-13,20] This makes the evidence difficult to interpret and apply to the generalized population regarding the true efficacy of these modalities in treating ED and PD.

Additionally, the marketing practices for these treatments do not adhere to existing treatment guidelines. The latest Candain Urological Association (CUA) recommendations advise against the use of Li-SWT for ED treatment, as it does not offer significant benefits, despite carrying minimal risk for the patient.[21] There may exist a role for Li-SWT in the resolution of pain associated with PD, but the CUA does not support the use of Li-SWT for reduction in penile curvature.[22] Similarly, the American Urological Association (AUA) guidelines express that Li-SWT is still being investigated for ED treatment, with PRP only warranting use as an experimental option.[23] Furthermore, the AUA states that Li-SWT is only applicable for pain management, but not curvature reduction. The AUA does not comment on the use of PRP in PD.[24]

The Sexual Medicine Society of North America advises against incorporating Li-SWT and PRP injections into routine clinical practice due to the lack of clinical trial evidence, despite recognizing the former as a relatively safe option.[25] Lastly, the European Association of Urology offers a weak recommendation on offering Li-SWT for mild vasculogenic ED or for patients not suitable for oral vasoactive agents and states it has no role to play in the reduction of plaque size or curvature. Using PRP therapy is still deemed experimental and limited to clinical trials for either ED or PD.[26]

With only 9.6% (n=7) of reporting clinics having a urologist present and 39.8% (n=29) lacking a physician affiliation, adherence to practice guidelines by these governing bodies may be challenging. While various professionals are qualified to deliver these treatments, it is essential to implement thorough patient assessment and counseling to ensure a well-informed treatment process, while maintaining patient autonomy and well-being. Currently, these therapies are being provided at high costs, tacking on considerable financial strain to the psychosocial burden being experienced by patients living with ED and PD.

Strengths and limitations

This study derives its strength from being the first to investigate the Canadian landscape on the availability of restorative therapies for ED and PD. We were able to provide preliminary data regarding unanswered questions, including the ownership and provider training of these clinics, the indications for treatment, cost structure, and transparency on success rates. This study further enhances our understanding of the landscape by comparing publicly available data with information directly obtained from clinics through contact.

The limitations of this paper revolve around its comprehensiveness, as many clinics may not be advertis-

ing their services online or explaining all relevant data points we intended to capture. Additionally, we did not follow through on the consultation process that many clinics asked for. Therefore, the team could not ascertain the consultation process that patients would face when initiating treatment or derive information that may have been provided throughout the consultation process. Despite these limitations, this study adds valuable insight into a geographic area that is largely understudied.

CONCLUSIONS

RTs are being marketed largely DTC across Canada. Many clinics, despite being open about their pricing and treatment options, still place a substantial financial strain on patients due to widely varying costs for therapies where data is still quite unclear. Future studies should continue to focus on unravelling the efficacy of these RTs and understanding the relationship between advertising and initiation of treatment, along with patient perspectives on the quality of information they are receiving regarding treatment options for ED and PD.

COMPETING INTERESTS: Dr. Patel has been a consultant for Boston Scientific. The remaining authors do not report any competing personal or financial interests related to this work.

This paper has been peer reviewed.

REFERENCES

1. Impotence: NIH Consensus Development Panel on Impotence. *JAMA* 1993;270:83-90. https://doi.org/10.1001/jama.1993.03510010089036
2. Ludwig W, Phillips M. Organic Causes of Erectile Dysfunction in Men Under 40. *Urol Int* 2013;92:1-6. https://doi.org/10.1159/000354931
3. Pryor J, Akkus E, Alter G, et al. Peyronie's Disease. *J Sex Med* 2004;1:110-115. https://doi.org/10.1111/j.1743-6109.2004.10116.x
4. Al-Thakafi S, Al-Hathal N. Peyronie's disease: A literature review on epidemiology, genetics, pathophysiology, diagnosis and work-up. *Transl Androl Urol* 2016;5:280-9. https://doi.org/10.21037/tau.2016.04.05
5. Stuntz M, Perlaky A, Vignes F des, et al. The prevalence of Peyronie's Disease in the United States: A population-based study. *PLoS One* 2016;11:e0150157. https://doi.org/10.1371/journal.pone.0150157
6. Rizk PJ, Krieger JR, Kohn TP, et al. Low-intensity shockwave therapy for erectile dysfunction. *Sex Med Rev* 2018;6:624-30. https://doi.org/10.1016/j.sxmr.2018.01.002
7. Man L, Li G. Low-intensity extracorporeal shock wave therapy for erectile dysfunction: A systematic review and meta-analysis. *Urology* 2018;119:97-103. https://doi.org/10.1016/j.urology.2017.09.011
8. Sokolakis I, Hatzichristodoulou G. Clinical studies on low intensity extracorporeal shockwave therapy for erectile dysfunction: A systematic review and meta-analysis of randomised controlled trials. *Int J Impot Res* 2019;31:177-194. https://doi.org/10.1038/s41443-019-0117-z
9. Patel P, Katz J, Lokeshwar SD, et al. Phase II randomized, clinical trial evaluating 2 schedules of low-intensity shockwave therapy for the treatment of erectile dysfunction. *Sex Med* 2020;8:214-22. https://doi.org/10.1016/j.esxm.2020.01.010
10. Poulios E, Mykoniatis I, Pyrgidis N, et al. Platelet-rich plasma for the treatment of erectile dysfunction: A systematic review of preclinical and clinical studies. *Sex Med Rev* 2023;11.
11. Alkandari MH, Touma N, Carrier S. Platelet-rich plasma injections for erectile dysfunction and Peyronie's Disease: A systematic review of evidence. *Sex Med Rev* 2022;10:341-52. https://doi.org/10.1016/j.sxmr.2020.12.004
12. Masterson TA, Molina M, Ledesma B, et al. Platelet-rich plasma for the treatment of erectile dysfunction: A prospective, randomized, double-blind, placebo-controlled clinical trial. *J Urol* 2023;210:154-61. https://doi.org/10.1097/JU.0000000000003481
13. Lu Z, Lin G, Reed-Maldonado A, et al. Low-intensity Extracorporeal shock wave treatment improves erectile function: A systematic review and meta-analysis. *Eur Urol* 2017;71:223-33. https://doi.org/10.1016/j.eururo.2016.05.050
14. Yang SC, Weinberger JM, Shahinyan RH, et al. Regenerative therapies for erectile dysfunction: The influence of direct-to-consumer marketing on patient interest. *Transl Androl Urol* 2023;12:586-93. https://doi.org/10.21037/tau-22-309
15. Bella AJ, Lee JC, Carrier S, et al. 2015 CUA Practice guidelines for erectile dysfunction. *Can Urol Assoc J* 2015;9:23-9. https://doi.org/10.5489/cuaj.2699
16. Kessler A, Sollie S, Challacombe B, et al. The global prevalence of erectile dysfunction: A review. *BJU Int* 2019;124:587-99. https://doi.org/10.1111/bju.14813
17. Eardley I. The incidence, prevalence, and natural history of erectile dysfunction. *Sex Med Rev* 2013;1:3-16. https://doi.org/10.1002/smrj.2
18. Layton JB, Kim Y, Alexander GC, et al. Association between direct-to-consumer advertising and testosterone testing and initiation in the United States, 2009-2013. *JAMA* 2017;317:1159-66. https://doi.org/10.1001/jama.2016.21041
19. McKinlay JB, Trachtenberg F, Marceau LD, et al. Effects of patient medication requests on physician prescribing behaviour: Results of a factorial experiment. *Med Care* 2014;52:294-99. https://doi.org/10.1097/MLR.0000000000000096
20. Poulios E, Mykoniatis I, Pyrgidis N, et al. Platelet-rich plasma (PRP) improves erectile function: A double-blind, randomized, placebo-controlled clinical trial. *J Sex Med* 2021;18:926-35. https://doi.org/10.1016/j.jsxm.2021.03.008
21. Domes T, Najafabadi BT, Roberts M, et al. Canadian Urological Association guideline: Erectile dysfunction. *Can Urol Assoc J* 2021;15:310-22. https://doi.org/10.5489/cuaj.7572
22. Bella AJ, Lee JC, Grober ED, et al. 2018 Canadian Urological Association guideline for Peyronie's disease and congenital penile curvature. *Can Urol Assoc J* 2018;12:E197. https://doi.org/10.5489/cuaj.5255
23. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: AUA Guideline. *J Urol* 2018;200:633-41. https://doi.org/10.1016/j.juro.2018.05.004
24. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. *J Urol* 2015;194:745-53. https://doi.org/10.1016/j.juro.2015.05.098
25. Liu JL, Chu KY, Gabrielson AT, et al. Restorative therapies for erectile dysfunction: Position statement from the Sexual Medicine Society of North America (SMSNA). *Sex Med* 2021;9:100343. https://doi.org/10.1016/j.esxm.2021.100343
26. Salonia A, Bettocchi C, Capogrosso P, et al. EAU guidelines on sexual and reproductive health. *Eur Urol* 2023:312. https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Sexual-and-Reproductive-Health-2023.pdf

CORRESPONDENCE: Dr. Premal Patel, Section of Urology, Health Sciences Centre, University of Manitoba, Winnipeg, MB, Canada; ppatel5@hsc.mb.ca