Cost-effectiveness analysis reveals microsurgical varicocele repair is superior to percutaneous embolization in the treatment of male infertility

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Abstract

Introduction: Varicoceles are a common cause of male infertility; repair can be accomplished using either surgical or radiological means. We compare the cost-effectiveness of the gold standard, the microsurgical varicocele repair (MV), to the options of a non-microsurgical approach (NMV) and percutaneous embolization (PE) to manage varicocele-associated infertility.
Methods: A Markov decision-analysis model was developed to estimate costs and pregnancy rates. Within the model, recurrences following MV and NMV were re-treated with PE and recurrences following PE were treated with repeat PE, MV or NMV. Pregnancy and recurrence rates were based on the literature, while costs were obtained from institutional and government supplied data. Univariate and probabilistic sensitivity-analyses were performed to determine the effects of the various parameters on model outcomes.
Results: Primary treatment with MV was the most cost-effective strategy at $5402 CAD (Canadian)/pregnancy. Primary treatment with NMV was the least costly approach, but it also yielded the fewest pregnancies. Primary treatment with PE was the least cost-effective strategy costing about $7300 CAD/pregnancy. Probabilistic sensitivity analysis reinforced MV as the most cost-effective strategy at a willingness-to-pay threshold of >$4100 CAD/pregnancy.
Conclusions: MV yielded the most pregnancies at acceptable levels of incremental costs. As such, it is the preferred primary treatment strategy for varicocele-associated infertility. Treatment with PE was the least cost-effective approach and, as such, is best used only in cases of surgical failure.

Introduction

Infertility affects about 15% of couples in the United States, with approximately 50% due to a male factor.[1] Consisting of a dilated and tortuous conglomeration of refluxing pampiniform plexus veins, varicoceles are present in 15% of the general population, about 35% of men with primary infertility and 80% of those with secondary infertility.[2-4] While varicoceles are the most easily treatable cause of male infertility, these vascular malformations are associated with a progressive worsening of testicular function if left untreated.[5-7] Varicocele repair improves semen quality and sperm DNA integrity,[8] increases clinical pregnancy and live birth rates during in-vitro fertilization (IVF) via intra-cytoplasmic sperm injection (ICSI)[9] and potentially recovers semen parameters in men with nonobstructive azoospermia.[10,11] While the effects of varicocele repair are well-established, the method of correction that is most cost-effective, is controversial.

Numerous surgical techniques exist to correct varicocele-induced infertility. The current gold standard is the open microsurgical varicocele repair (MV) via either an inguinal or sub-inguinal incision. Both approaches allow for the spermatic cord to be delivered into the incision, making it easy to identify the artery, veins and lymphatics.[2] In a recent review, the microsurgical subinguinal technique was found to yield the highest pregnancy rates, fewest recurrences and lowest complication rates.[4] Another surgical option, the non-microsurgical varicocele repair (NMV), is still currently practiced, but is not considered to be standard of care.[2]

Another, non-surgical treatment option for varicocele repair is percutaneous embolization (PE). Typically performed by an interventional radiologist, PE is the selective embolization of gonadal veins. Using coils, PE has the suggested advantages of faster recovery time and protection of the testicular artery without the requirement for anesthesia. PE is unfortunately accompanied by higher failure rates (4%-11%) and increased rates of recurrences.[2] Studies have identified similar improvements in semen parameters and pregnancy rates compared to surgical correction.[12-14] Interestingly, a recent retrospective review of 158 patients post-PE noted very low failure rates for unilateral, left-sided

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embolization prompting the authors to suggest that men with unilateral left-sided varicoceles could be offered either MV or a PE with good expectant outcomes.[15]

When considering varicocele repair in the modern era, the rise of assisted reproductive technology (ART) needs to be considered. The widespread expansion of IVF has resulted in patients with a correctible varicocele offered immediate IVF instead of male factor treatment.[1] While IVF is effective, this ART approach is still very expensive and has implications for both the offspring and mother, including multiple gestations, low birth weights and possibly increased birth defects.[1] Moreover, in a recent decision analysis by Meng and colleagues,[1] varicocele repair was more cost effective than ART while, at the same time, providing comparable live birth rates.[1] Moreover, in cases of varicocele-associated infertility, immediate IVF should rarely be considered as the favoured treatment strategy.[16] Indeed, the results of these previously cited studies have almost uniformly demonstrated that initial correction of the underlying cause is the more cost-effective strategy.[16,17]

To date, there are very few studies comparing different methods of surgical correction to themselves and/or to PE. There is a further paucity in the literature with respect to decision analysis and cost-effectiveness regarding these different approaches. As such, the purpose of our current study was to comprehensively analyze the cost-effectiveness of various surgical approaches available to correct varicocele-associated male infertility. Specifically, we employed a decision-analysis model to determine whether MV, MNV or PE would yield the best treatment strategy with respect to costs, complications, fertilization and live birth rates.

Methods

Model design

Classification of treatment arms was determined based on currently accepted techniques and a review of recent literature.[15,18-20] The various strategies include NMV, MV and PE (Table 1). The treatment strategies were organized with decision arms progressing from primary to secondary treatment approaches over time (Fig. 1). Exclusion of the retroperitoneal, scrotal and laparoscopic options was made given the relative infrequency with which these surgeries were performed and the associated lack of comprehensive costing and outcomes.[21,22]

A decision tree was constructed (Fig. 1) using decision analysis software (TreeAge Pro Healthcare 2009, TreeAge Software Inc., Williamstown, MA.). Each treatment strategy

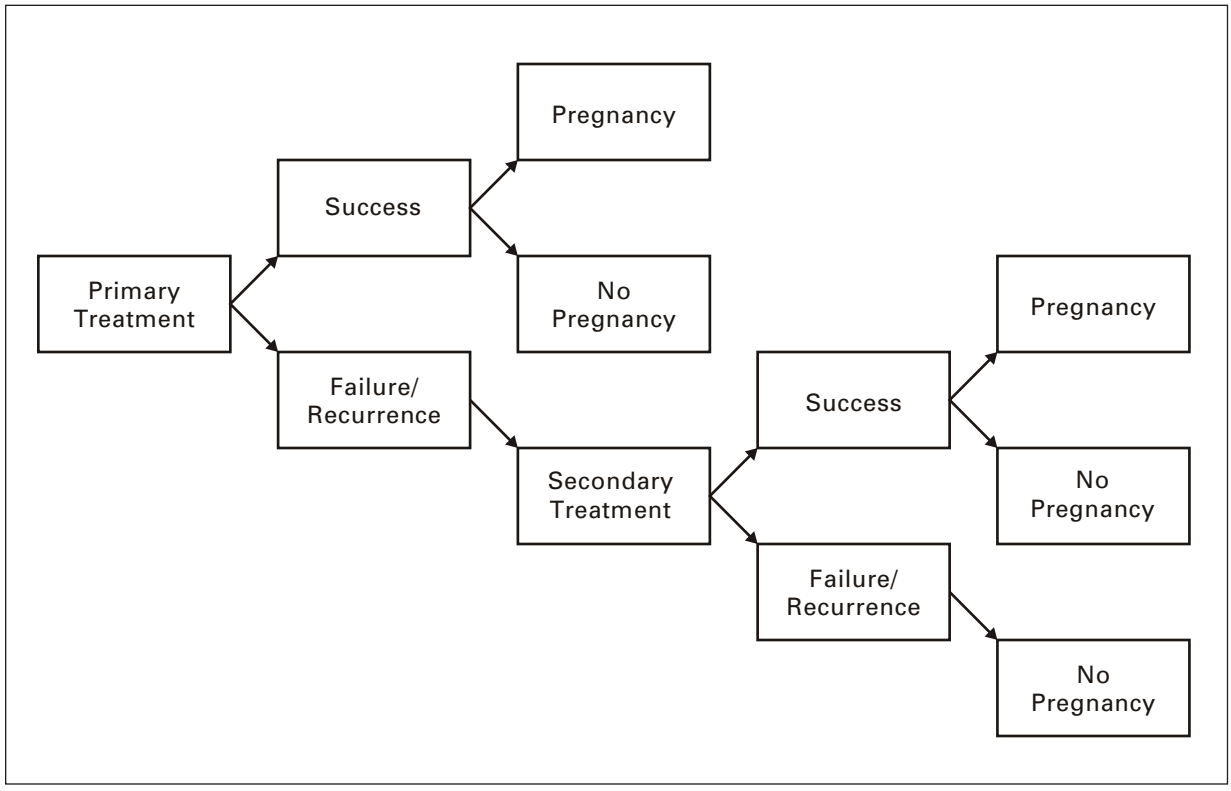

Fig. 1. Decision tree.

Table 1. Treatment arms

Treatment strategy	Primary treatment	Secondary treatment
1	NMV	PE
2	MV	PE
3	PE	NMV
4	PE	MV
5	PE	PE

NMV: non-microsurgical approach; PE: percutaneous embolization; MV: microsurgical varicocele repair.

consisted of a primary treatment followed by a secondary treatment for recurrences or treatment failures (Table 1, Fig. 1). The decision to exclude surgical approaches (NMV, MV) as secondary treatments for primary treatment surgical failures (Table 1) was made given the lack of literature available for this treatment condition. A Markov simulation cycle was then developed to estimate costs and pregnancy rates, as well as to evaluate each type of procedure (NMV, NMV and PE). Within the model, recurrences following MV and NMV were re-treated with PE and recurrences following PE were treated with repeat PE, MV or NMV (Fig. 1). Primary or secondary treatments complicated by a hydrocele could then proceed to hydrocele repair. Other complications of varicocele repair were excluded from the model. The time to progress from the start of the decision tree to the Markov cycle was considered immediate and no time was accrued during this period. Costs, pregnancy rates and recurrence-free rates were computed for each treatment strategy by performing 10 000 Monte Carlo micro-simulations.

Model data sources

Probability estimates

Varicocele recurrence rates (Table 2a), pregnancy rates (Table 2b) and hydrocele formation rates (Table 2c) following MV, NMV and PE were obtained from a pooled analysis of 33 studies evaluating varicocele repair outcomes by Diegidio and colleagues.[4] Reported recurrence rates were assumed to represent both recurrences and treatment failures.

Estimated recurrence rates following NMV, MV and PE as primary treatments were 15.7%, 2.1% and 4.3%, respectively (Table 2a). Recurrence rates following each procedure as a secondary treatment was estimated as 110% of their respective primary recurrence rate. This was done to reflect a possible decreased success rate in patients already demonstrating a predilection to recurrence as previously described.[23,24]

Table 2a. Recurrence rates

Technique	Mean (%)	Range (%)
NMV	15.7	3.6–17.5
MV	2.1	0.7–15.2
PE	4.3	3.6–17.5

NMV: non-microsurgical approach; PE: percutaneous embolization; MV: microsurgical varicocele repair.

Estimated pregnancy rates following NMV, MV and PE were 30.1%, 44.8% and 31.9%, respectively (Table 2b). In simulations where a secondary treatment was required for recurrence, the pregnancy rate was estimated as the lesser of the primary and secondary procedure types.

Estimated hydrocele formation rates following NMV, MV and PE were 7.5%, 0.7% and 0%, respectively (Table 2c). Reports describing the frequency that patients with post-varicocele repair hydroceles pursued repair was not available; however, we estimated this frequency as 25% based on expert opinion. All hydrocele repairs were assumed to be successful and the complications of the hydrocele repair were not considered.

Cost estimates

Costs were estimated from a payer perspective. Detailed cost derivations in Canadian and US (United States) dollars were determined and summarized (Table 3a, Table 3b). US dollar costs were based on current (2013) conversion rates. The direct costs of NMV, MV and PE were estimated from a retrospective review of institutional cost data at a Canadian Hospital.

Hospital costs included the use of operating room, operating room personnel, surgical equipment, disposables, use of post-anesthetic recovery room and medications used in hospital (Table 3a, Table 3b). The surgeon, radiologist and anesthesia fees were based on the 2012 Ontario Health Insurance Plan (OHIP) fee schedule (Table 3a, Table 3b).[25] All procedures were assumed to be outpatient procedures requiring no hospital admission. The capital cost and depreciation of the operative microscope was not considered since it is typically available at most institutions with costs

Table 2b. Pregnancy rates

Technique	Mean (%)	Range (%)
NMV	30.1	20.0–31.5
MV	44.8	33.8–51.5
PE	31.9	12.2–40.0

NMV: non-microsurgical approach; PE: percutaneous embolization; MV: microsurgical varicocele repair.

Table 2c. Hydrocele rates

Technique	Mean (%)	Range (%)
NMV	7.5	4.3–17.5
MV	0.7	0.0–1.6
PE	0.0	0.0

NMV: non-microsurgical approach; PE: percutaneous embolization; MV: microsurgical varicocele repair.

Table 3a. Cost estimates for NMV and MV*

	NMV	MV
Hospital costs	$1175 (range: $702–1619) ($1184 USD)	$1711.13 (range: $1224.56–3304.56) ($1723.80 USD)
Surgeon fee	$205.35 ($206.87 USD)	$205.35 ($206.87 USD)
Anesthesia fee	$225.15 ($226.82 USD)	$315.21 ($317.54 USD)
Total cost	$1605.50 ($1617.39 USD)	$2231.69 ($2248.21 USD)

*Cost $ CAD ($US). NMV: non-microsurgical approach; MV: microsurgical varicocele repair.

shared among several surgical services.

Indirect patient costs included costs of outpatient analgesia routinely prescribed and health-related productivity loss (HRPL) or societal costs (Table 4a, Table 4b). HRPL was calculated by incorporating the mean time off work (Table 4a) multiplied by the mean Canadian hourly wage for males (Table 4b). The mean time off work and the average wages were obtained from Canadian Government source documents. The costs of the operative hydrocele repair were calculated using similar methodologies.

Univariate and probabilistic sensitivity analysis

The robustness of our model to variations in key parameters was first analyzed by performing a univariate sensitivity analysis. Each parameter was individually varied across a clinically plausible range of values and the outcome of the model was recalculated throughout this range. Although univariate sensitivity analysis can identify the relative influence of individual parameters on model outcome, it inadequately reproduces real-world variability where multiple parameters may change simultaneously.

We thus addressed these limitations by performing a probabilistic sensitivity analysis, which realistically reflects real world uncertainty by varying each model parameter simultaneously. This analysis was done by substituting each parameter estimate with a probability distribution and by performing a Monte Carlo simulation. In these simulations, we estimated a theoretical patient's progress through the decision analysis model with parameter values randomly drawn from each probability distribution. Thus, probability distributions were created around each parameter using the variance reported in the literature.[26]

Table 4a. Societal costs

Technique	Mean (days)	Range (days)
NMV	6.6	3–9
MV	4.8	1–8
PE	1.0	NA

NMV: non-microsurgical approach; PE: percutaneous embolization; MV: microsurgical varicocele repair; NA: not available.

Table 3b. Cost estimates for PE*

Hospital costs	$1907.94 (range: $1840.65–2477.45) ($1922.07 USD)
Radiologist fee	$317.40 ($319.75 USD)
Anesthesia fee	$0 ($0 USD)
Total cost	$2225.34 ($2241.82 USD)

*Cost $ CAD ($US). PE: percutaneous embolization.

Clinically plausible estimates of variance were used when no published variance data were available.[26] Following standard conventions, costs were modelled with gamma distributions and transition probabilities were modelled with beta distributions. The results of 1000 Monte Carlo simulations were plotted on a cost-effectiveness axis. A cost-effectiveness acceptability curve (CEAC) was then generated by determining the percentage of simulations that remained cost-effective over a range of willingness-to-pay (WTP) thresholds. Reported WTP thresholds, which reflect the highest additional cost infertile couples are willing to pay for one additional pregnancy, ranged from $15 000 to $65 000 USD.[4,16,26] There is currently no consensus on society's WTP threshold for providing an infertile couple with one additional pregnancy.

Results

The results of the index case cost-utility analysis are summarized in Table 5. PE followed by PE was the least costly strategy at $2538 CAD, but had the second lowest pregnancy rate at 0.319 pregnancies. MV followed by PE was the strategy that achieved the highest pregnancy rate (0.444), although it did so at a higher cost ($3271 CAD). Adjusting the cost per pregnancy, MV-PE was superior at a cost of $7363 CAD per pregnancy. The incremental cost-effectiveness ratio (ICER) of MV-PE was $5569 CAD per pregnancy. Given a WTP range from $15 000 to $65 000 CAD, this highlights MV-PE as the preferred strategy with a higher effectiveness versus cost ratio (Fig. 2).

The remaining strategies: PE-NVM, PE-MV and NMV-PE all failed to show any increase in pregnancy rate compared to MV-PE (0.316, 0.319, 0.299, respectively). The higher associated costs of PE-NVM, PE-MV and NMV-PE compared to PE-PE resulted in higher costs per pregnancy.

Recurrence, pregnancy and hydrocele rates following NVM, MV, and PE were described above in Table 2a, Table 2b and Table 2c. Using a WTP of $15 000 to $60 000 CAD, MV-PE was the preferred strategy at all ranges of sam-

Table 4b. Lost wages

Average wage (per hour)	Work hours (per day)	Average wage (per day)
$25.58 CAD ($25.77 US)	8	$204.64 CAD ($206.16 US)

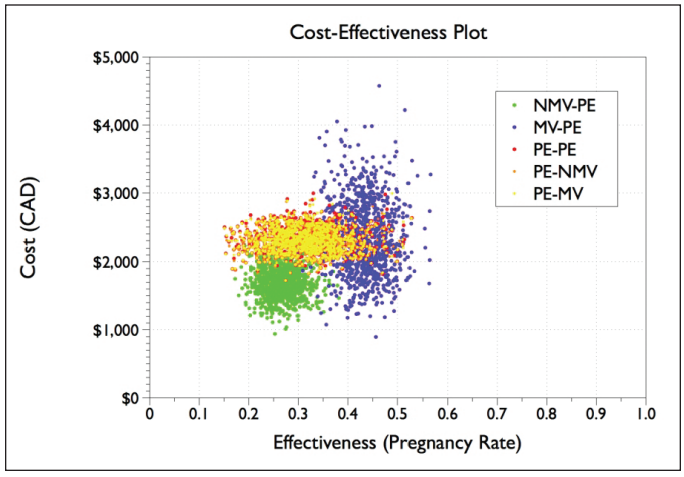

Fig. 2. A cost-effectiveness plot demonstrating the superiority of microsurgical varicocele repair-percutaneous embolization (MV-PE) as the most cost-effective treatment approach.

pled parameters. The cost-effectiveness acceptability curve (CEAC) (Fig. 3) shows a change from PE-PE at $5790 USD to MV-PE. Using a WTP of $15 000 to $60 000 CAD, it can be concluded that MV-PE is the most cost-effective strategy.

Discussion

Our study demonstrates that in varicocele-associated causes for male infertility, MV resulted in higher pregnancy rates than any of the other treatment strategies. In addition, it did so with an acceptable ICER ($5569/pregnancy), making it the most cost-effective strategy in our decision-analysis. PE was not as cost-effective and should therefore be saved for varicoceles that have previously failed surgical management. Both strategies are within the WTP threshold of $15 000 to $60 000 CAD with MV-PE still preferred. MV-PE is still preferred in part because of the higher success rates and ultimately, the lower achievable costs per pregnancy. Both PE and MV were far superior to NVM given the increased cost per pregnancy and highest complication rates.

To our knowledge, no randomized, controlled clinical studies comparing the outcomes of the different treatment methods for varicocele repair currently exist. In a recently performed prospective, randomized clinical trial, subinguinal MV resulted in improved semen analysis parameters, as well as enhanced rates of spontaneous pregnancies when compared to observation (13.9% vs. 32.9%) with a number needed to treat of 5.27.[27] A meta-analysis performed by Cayan and colleagues in 2009[28] is currently the benchmark for comparison. The authors analyzed 36 studies from 1980 to 2008 and showed that spontaneous pregnancy rates using MV were 41.97%. This was significantly greater than the 33.2% using PE[28] and similar to the results that we have obtained using our model. Moreover, Cayan and colleagues[28] also demonstrated that NMV had a spontaneous pregnancy rate of 36%, a recurrence rate 2.63%, and a hydrocele formation rate of 7.3%. The laparoscopic technique, which was not included in the current study, has a less successful 30.07% spontaneous pregnancy rate with a recurrence rate of 4.3%. Given the significantly inferior pregnancy rates obtained using a laparoscopic approach, it was excluded from our study.[28]

With regards to cost-effectiveness, several studies have been performed looking at male infertility secondary to the presence of a varicocele. An early study by Schlegal and colleagues in 1997[17] evaluated whether using ART as the primary method of treatment for varicocele-associated male infertility was more cost-effective compared to surgical correction. When male factor infertility was bypassed via direct treatment using ART, men with varicoceles had an average cost per successful delivery of $89 091 USD.[17] This was significantly more than the $26 268 USD cost per delivery for men who had their varicoceles surgically repaired prior to ART.[17] The authors concluded that specific treatment for varicocele-associated infertility with surgical repair was more cost-effective than primary treatment with ART. More recently, Penson and colleagues[16] noted similar findings: immediate IVF was not as cost-effective as varicocele repair followed by IVF. Specifically, immediate IVF accrued average costs of $20 394 USD, with a live birth effectiveness probability of 0.61.[16] This was more expensive and less effective than initial varicocele repair followed by IVF ($15 980 USD, effectiveness probability = 0.72).[16] Interestingly, when the couples were 'treated' with observation (assumed to be at a cost of $0), the cost per live pregnancy was, as would be expected, substantially less than varicocele repair followed by IVF. Given that observation alone was effective 14% of the time, the cost-savings occurred at the expense

Table 5. Index case cost-utility analysis

Treatment strategy	Cost $CDN ($USD)	Pregnancy rate	Cost per pregnancy, cost $CDN ($USD)	ICER, cost $CDN ($USD)
PE–PE	$2538 ($2557 USD)	0.319	$7964 ($8023 USD)	—
PE–NMV	$2565 ($2584 USD)	0.316	$7964 ($8023 USD)	Dominated
PE–MV	$2574 ($2593 USD)	0.319	$8068 ($8128 USD)	$122 775/pregnancy ($123684 USD)
MV–PE	$3271 ($3295 US)	0.444	$7363 ($7418 USD)	$5569/pregnancy ($5610 USD)
NMV–PE	$3412 ($3437 USD)	0.299	$11 429 ($11 514 USD)	Dominated

NMV: non-microsurgical approach; PE: percutaneous embolization; MV: microsurgical varicocele repair; NA: not available; ICER: incremental cost-effectiveness ratio.

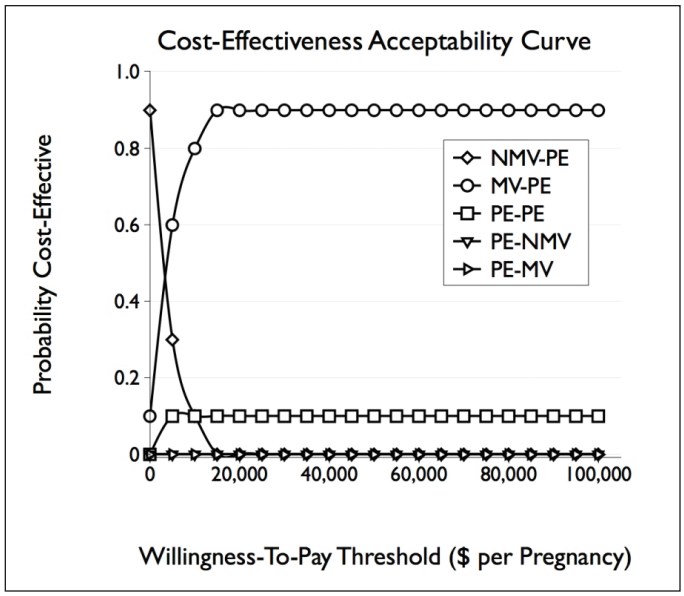

Fig. 3. The cost-effectiveness acceptability curve concluding that microsurgical varicocele repair-percutaneous embolization (MV-PE) is the most cost-effective strategy.

of success.[16] When multiple pregnancies were considered, varicocele repair followed by IVF dominated immediate IVF without surgical repair.[16]

While we did not consider multiple pregnancies within our decision analysis model, the current study has other limitations. Similar to all models of decision analysis, the quality of data is highly reliant on the information used to populate the model. Since there is a limited amount of literature comparing PE to MV, most of our data came from a single pooled analysis of 33 studies.[4] Thus, to strengthen our limited data, we used a comprehensive sensitivity analysis to minimize the uncertainty. Ideally, a multicentre randomized control trial comparing the cost of MV and PE, along with their respective spontaneous pregnancy rates, could be used to resolve the controversy. Further limitations include the fact that the costing was done based on the data from a single Canadian centre. As such, variability would be expected both regionally and internationally.

Conclusion

In the current study, the cost-effectiveness of surgical varicocele repair was compared to PE. MV yielded the greatest number of pregnancies at an acceptable level of incremental cost. Based on these findings, MV should be the first-line treatment for varicocele-related infertility. Conversely, we found that PE is best reserved to treat varicoceles refractory to surgical management.

Competing interests: Dr. Kovac, Dr. Fantus. Dr. Lipshultz, Dr. Fischer and Dr. Klinghoffer all declare no competing financial or personal interests.

This paper has been peer-reviewed.

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