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SYSTEMATIC REVIEW

Safety and effectiveness of the different types of embolic materials for the treatment of testicular varicoceles: a systematic review

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Objective: The purpose of this study is to assess the current evidence regarding the safety and effectiveness of the various embolic materials used in varicoceles embolization.

Methods: A systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. Databases were searched for clinical studies that investigated the clinical outcomes of embolization treatment for the management of testicular varicoceles. Study methodological quality was analyzed.

Results: 23 retrospective and 7 prospective clinical studies were identified with a total of 3505 patients. Technical success rates appear to be above 90% for all embolic materials without any significant differences. In terms of recurrence rates, glue ($N = 251$) appeared to have the lowest and sclerosants alone ($N = 728$) the highest recurrence rates which were 4.2% (11–3.08%, SD: 5.9) and 11.03% (18.8–5.15%, SD: 6.06) within an average follow up (f/u) of 16.13 and 25.48 months respectively. Coils alone ($N = 898$) had an average recurrence rate of

9.1% (17.8–1.4%; SD: 5.79) and a mean f/u of 39.3 months. After an average of 12 months of f/u, the addition of sclerosants ($N = 1628$) as an adjunct to coils did not improve recurrence rates (8.44%, 16.5–5.1%; SD: 3.4). No differences were reported regarding the safety profile of the various embolic materials.

Conclusion: Despite the heterogeneity of the included studies, preliminary evidence supports the safe and effective use of the various embolic materials currently used for the management of varicoceles. At 1 year, glue appears to be the most effective in preventing recurrence with coils being the second most effective. The addition of sclerosants to the coil embolization did not appear to have an impact on recurrence rates. Further research is required to elucidate the cost-effectiveness of these approaches.

Advances in knowledge: Varicocele embolization appears to be a safe and effective technique regardless of the embolic agent. Addition of a sclerosant agent to coil embolization does not appear to improve outcomes.

INTRODUCTION

Varicoceles are abnormal dilatations of the pampiniform venous plexus draining the testicles.¹ The incidence of varicoceles in the normal healthy males is estimated to be 8–23% with the majority of cases affecting the left side.^{2–4} The etiology of idiopathic varicoceles is still unknown but they are associated with infertility,⁵ and as a result often even idiopathic varicoceles that are not causing symptoms may still need treatment.^{3,4} Surgery has been used to treat varicoceles for over a century⁶ but over the last few decades, radiological techniques have become increasingly popular as a less invasive technique,⁷ initially used when surgery failed but now a technique in its own right to treat varicoceles.

The role of the varicoceles in male infertility was highlighted early by several authors, who described a variety of surgical techniques such as inguinal or subinguinal operative approach⁸ and the most recent laparoscopic approach.⁹ Percutaneous embolization was first described in 1978 by Lima et al⁷ and consists the least invasive approach. A significant number of articles has proven its efficacy, especially in improving sperm count values, pregnancy outcomes and pain discomfort to the patients. Interventional treatment offers the potential advantages of less patient discomfort and rapid recovery.^{10–12}

Embolic agents, which are commonly used for varicocele embolization, are mechanically occlusive solid and liquid embolic agents such as coils, sclerosants and glue. The

Figure 1. Flow chat demonstrating the search strategy for this study.

purpose of this study is to review and compare the available clinical evidence regarding the safety and effectiveness of the various types of embolic materials for the management of varicoceles.

METHODS AND MATERIALS

We conducted a systematic review according to the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement. We performed a literature research in PubMed, Scopus and Cochrane databases by using the following key terms: “varicocele embolization”, “interventional radiology”, AND “varicoceles” OR “embolic materials” in various combinations.

Two investigators (GCM and EE) independently performed the literature search, study selection, data extraction and quality evaluation. In case of disagreement, there was a consensus meeting between all authors. Time or language of publication were not a restriction in our literature search, while all references of the obtained articles were also evaluated for any additional information. Our literature search was concluded on 1 November 2017 (Figure 1).

Study selection

Studies were included in the analysis if they met the following inclusion criteria: (1) included patients with testicular varicoceles (unilateral or bilateral); (2) included patients who were treated with venous embolization using glue, coils, sclerosants or combinations; (3) studies that included more than 10 patients and not case reports; (4) studies reporting clinical outcomes on effectiveness and safety; (5) prospective or retrospective study designs were also accepted; (6) irrelevant studies and studies without clinical outcomes or reports on safety were excluded. *In vitro* or animal studies as well as case reports were also excluded.

Data extraction

We extracted data about the number of patients included, study design, type of embolic material, technical success rates, recurrence rates and duration of follow. We also extracted information concerning perioperative and post-procedural complications.

Study quality assessment

A quality assessment analysis of all the non-randomized included studies was done using a Methodological Index for Non-Randomized Studies (MINORS).¹³ In the case of randomized studies, the methodology was assessed using the Coleman Methodology Score.¹⁴

Statistical analysis

The mean and SDs were calculated and when appropriate compared using *t*-test. The χ^2 test was also used when qualitative data were analyzed. Comparisons between the various embolic materials were performed using a *p* value < 0.05.

RESULTS

We identified 207 studies, 30 of which met the inclusion criteria with a total of 3505 patients. 23 of the studies were retrospective and 7 were prospective. In majority of the studies ($N = 13$), coils were used, which was followed by the use of coils in combination with sclerosants ($N = 10$ studies) and then by sclerosants alone ($N = 5$). Glue was also used but only on four studies (Table 1).

The technical success rates were above 92% for all embolic materials without any significant differences. More specifically, the use of sclerosants was evaluated in a total of 728 patients with a mean follow up time of 25.5 months.^{10,12,17,27,41} The average technical success rate was 92.5% (range: 100–80.2%, SD: 7.58), whereas the relapse rate in this group was on average 11.03% (range: 18.8–5.15%, SD: 6.06). Fever, epididymo-orchitis, testicular or groin swelling or hydrocele were observed in 1.9% of the treated patients and they were the most frequently encountered complications in this group followed by spermatic vein rupture and extravasation (0.9%) and allergic reactions (0.2%). No need for reintervention was reported in this group and there was no associated mortality.

In total, 898 patients were treated with coils alone^{11,18,20,21,25,26,29,30,32,33,36,38,42} and 1,628 patients with a combination of coils and sclerosants.^{15,16,19,20,22,23,28,31,34,37} The coil group had a mean follow up of 39.3 months when in the combined treatment group this was 11.7 months. The mean technical success was 92% in both treatment groups when the average observed relapse rate was 9.1% (17.8–1.4%, SD: 5.79) for the coil group and 8.44% (16.5–5.1%, SD: 3.4) for the combined treatment group. There was no statistically significant difference between the two groups. In the coil group, epididymo-orchitis, pampiniform plexus phlebitis or hydrocele were observed in 3.4% of the patients and was the most common complication that was managed conservatively. There was also one reported case of coil migration to the right atrium, which had to be retrieved immediately and also one case of femoral phlebitis. In the combined treatment group the most common complication was spermatic vein rupture with contrast leakage in 0.8% of the patients,³⁵ followed by scrotal discomfort, pampiniform phlebitis or spermatic cord inflammation in 0.3% of the treated patients. Minor groin hematoma, acute abdominal pain and

Table 1. Clinical studies evaluating the use of different types of embolic material for the endovascular treatment of testicular varicoceles

Author	Study design	Type of embolic material	Number of patients (N)	Number of varicoceles	Technical success (%)	Recurrence rates (%)	Follow-up time (M)	Reported complications	MINORS/Coleman methodology score
Alhahtani et al ¹⁵	Observational study Retrospective	Sclerosants and coils	41	43	95.0%	9.70%	22	Pain, extravasation of contrast, dyskinetic movement, and vasovagal attack (N = 5)	13/16
Ali et al ¹⁰	Observational study Retrospective	Sclerosants	141	146	91.8%	16.10%	46.4	Contrast agent extravasation, and pampiniform plexus phlebitis (N = 1), temporary inguinal/scrotal swelling (N = 1), temporary minimal groin hematoma, of temporary pain in the flanks (N = 1).	12/16
Basile et al ¹⁶	Randomized controlled clinical trial Prospective	Sclerosants + coils	90	90	75.6–93.4%	6.7–11.2%	3	Vein rupture with contrast leakage (N = 10), minor groin haematoma (N = 7)	73/100
Bechara et al ¹¹	Comparative study Retrospective	Coils	41	41	95%	4.8%	n/a	NR	18/24
Beutner et al ¹⁷	Comparative study Retrospective	Sclerosants	101	126	80.20%	18.8%	69	Epididymo-orchitis (N = 6) Hydrocele (N = 2)	14/24
Cantoro et al ¹⁸	Non-randomized controlled study Prospective	Coils	218	218	91.30%	2.30%	39.4 ± 6.5	Epididymo-orchitis (N = 8)	18/24
Di Bisceglie et al ¹⁹	Non-randomized controlled study Prospective (treated group vs control)	Sclerosants and coils	223	240	n/a	7.60%	6	acute abdominal pain (N = 2), 2 spermatic cord inflammation (N = 2), vasovagal attack (N = 1)	16/24
Favard et al ²⁰	Comparative study Retrospective	Glue vs coils vs sclerosants and coils	182	203	only successful cases	11 vs 13.2 vs 6.0%	24.40	Pampiniform plexus phlebitis (N = 2), minor groin hematoma that resolved spontaneously (N = 4)	18/24
Ferguson et al ²¹	Observational study Retrospective	Coils	87	87	91.0%	n/a	24	NR	13/16
Flacke et al ²²	Observational study Prospective	Coils and sclerosants	223	228	99.10%	7.15%	3–1.2 years	NR	13/16

(Continued)

Table 1. (Continued)

Author	Study design	Type of embolic material	Number of patients (N)	Number of varicoceles	Technical success (%)	Recurrence rates (%)	Follow-up time (M)	Reported complications	MINORS/Coleman methodology score
Gandini <i>et al</i> ¹²	Observational study Retrospective	Sclerosants	244	280	97.1%	3.6–6.7%	40.3	Allergic reaction (N = 2), retroperitoneal leakage of contrast medium (N = 4), short episode of fever (N = 2), testicular swelling that resolved (N = 2)	12/16
Gazzera <i>et al</i> ²³	Observational study/ controlled study Prospective	Sclerosants and coils	223	223	92.30%	16.50%	6	Acute abdominal pain (N = 2), Vasovagal attacks during administration of sclerosing agent that resolved spontaneously (N = 3) spermatic cord inflammation that resolved within days after medical therapy (N = 2)	12/16
Heye <i>et al</i> ²⁴	Randomized clinical trial Prospective	Glue	64	66	100%	1.60%	12	Self-limited perforation of the left internal spermatic vein with (N = 11) with contrast extravasation	76/100
Keoghane <i>et al</i> ²⁵	Observational study Retrospective	Coils	50	50	94%	16%	3	Discomfort at follow up (N = 4)	11/16
Kim <i>et al</i> ²⁶	Observational study Retrospective	Coils	28	28	93%	(4) 16% partial; 1 unimproved case 4%	5d-54 (195d)	Pampiniform plexus phlebitis (N = 1)	11/16
Li <i>et al</i> ²⁷	Observational study Retrospective	Sclerosants	58	58	100%	8.6%	6	NR	12/16
Mazzoni <i>et al</i> ²⁸	Observational study Retrospective/peds	Sclerosants + coils	251	277	79.4%	n/a	6–24	NR	10/16
Nabi <i>et al</i> ²⁹	Observational study Retrospective	Coils	71	77	96%	1.40%	3–12	NR	13/16
Prasivoravong <i>et al</i> ³⁰	Observational study Retrospective	Coils	47	47	100%	n/a	3,6,12	NR	12/16
Polito <i>et al</i> ³¹	Observational study Retrospective	Coils and sclerosants	468	468	95.9%	5.1%	12	NR	12/16
Puche-Sanz ³²	Observational study Retrospective	Coils	154	154	95.5%	13.1%	39	Hydrocele (N = 7), femoral phlebitis (N = 1)	12/16

(Continued)

Table 1. (Continued)

Author	Study design	Type of embolic material	Number of patients (N)	Number of varicoceles	Technical success (%)	Recurrence rates (%)	Follow-up time (M)	Reported complications	MINORS/Coleman methodology score
Punekar et al ³³	Observational study Retrospective	Coils	39	39	85.0%	n/a	n/a	NR	10/16
Reiner et al ³⁴	Observational study Retrospective	Coils and sclerosants	16	16	100%	6%	2–12	Scrotal discomfort and pampiniform phlebitis (N = 1)	11/16
Rivilla et al ³⁵	Observational study Retrospective	Coils	20	20	100%	5%	9–13 years	Phlebitis of the pampiniform plexus (N = 13), contrast extravasation around the spermatic vein (N = 3)	13/16
Sivanathan et al ³⁶	Observational study Retrospective	Coils	40	40	77.1%	8.5%	1–6 years, mean 1.1	Migration of coil to right atrium which was captured and removed immediately (N = 1), Right leg pain (N = 1), abdominal pain during the procedure (N = 1)	13/16
Storm et al ³⁷	Observational study Retrospective	Coils and sclerosants	27	27	92.5%	9%	9	NR	12/16
Tanahatote et al ³⁸	Non-randomized controlled study Retrospective, control group (50 vs 11)	Coils	50	61	n/a	n/a	n/a	NR	17/24
Vanlangenhove et al ³⁹	Randomized controlled trial prospective	Glue	83	112	70.7–83.3%	n/a	n/a	Acute allergic reaction immediately after embolization (N = 1)	78/100
Urbano et al ⁴⁰	Observational study Retrospective	Glue	41	42	100%	0%	12	Moderate post-embolization pain (N = 7) that required oral analgesic treatment for 7–10 days.	12/16
Zampieri et al ⁴¹	Observational study Retrospective	Sclerosants	184	184	93.4%	6.50%	3	Self limited venous perforation with consequent spillage of the contrast agent (N = 2).	11/16

M, months; MINORS, Methodological Index for Non-Randomized Studies; O–16 for non-comparative studies, O–24 for comparative studies; N, Number of patients; NR, not reported; vs, versus; %, percentage.

vasovagal attacks were also reported in 0.4, 0.3 and 0.2%, respectively.

Glue as an embolic material was the least used with 251 patients studied in total.^{20,24,39,40} The average technical success rate was 92% (100–77%, SD: 13.2) and the average recurrence rate was 4.2% (11–0%, SD: 5.9). The patients were followed up for an average of 16.13 months. Perforation of the internal spermatic vein with contrast extravasation was the most common complication occurring in 5.8% of the patients. Moderate post-embolization pain was also reported in 3.7% of the patients. Acute allergic reaction immediately after embolization was reported in only one case. Once again, no associated mortality or need for reintervention was reported. When comparing complications rates between the various embolization material glue was associated with a significantly higher risk of spermatic vein perforation the risk in comparison to other techniques ($p < 0.05$) with, though, no increase in the need for reintervention. Post-embolization pain also appeared to be reported as a complication more frequently in the glue group in comparison to the other groups ($p < 0.05$).

Pain levels were reported in six studies.^{10,12,20,24,26,32} There was significant heterogeneity regarding the pain assessment scores and due to that it was not possible to perform comparisons between the various embolic materials before and after treatment. However, all studies reported improved pain scores post-embolization. Fertility outcomes were also reported in 12 studies^{10,12,18,19,21–23,29–31,33,42} with significant heterogeneity in the reported outcomes. Four studies reported outcomes on the frequency of successful pregnancies, which ranged between and 3363%.^{10,18,29,33} Potential improvement in sperm characteristics were evaluated in 11 studies, all of which reported statistically significant improvement in sperm count and/or sperm motility.^{12,18,19,21–23,29–31,33,42} Due to the heterogeneity of reported outcomes, again it was not possible to perform comparisons between the various embolic materials.

The quality analysis of the included studies showed that for the randomized controlled trials the scores were ranging between 73 and 78/100 on the Coleman methodology score. For the purely observation studies, the MINORS score ranged between 11 and 13, when 16 was considered to be the maximum score. Finally, for the comparative studies the MINORS score ranged 14–18, when 24 was considered as the maximum score.

DISCUSSION

The purpose of this systematic review was to systematically review and assess the available evidence around the use of different embolic materials in the treatment of testicular varicoceles. Different embolic materials are widely used in the management of varicoceles aiming to reduce the complications and increase the pregnancy rates.

Currently, the choice of embolic agent depends on operator preference and experience.⁴³ Our systematic review shows that there is still a wide variation in the practice of varicoceles embolization. The combination of coils and sclerosants appear to be the

most popular treatment option followed by the use of coils or sclerosants as single agents. Interestingly, the use of glue appears more limited with only 8% of the patients included in our analysis having been treated with glue.

Technical success rates were similar in all treatment groups with all of them averaging above 90% proving that embolization can be an easily reproducible technique regardless of the embolic material. Regarding recurrence, glue appeared to have the lowest recurrence rate with less than 5%. Mechanical embolization with coils or sclerosants or combinations resulted in higher recurrence rates (8–11%) in the long run (the average follow-up time was 25 months). Interestingly, it was noted that the combination of coils and sclerosants did not improve the recurrence rates when compared to coils alone. In addition, in our systematic review of the data, only one study²² was identified having performed direct comparisons between the use of coils/plugs, sclerosants and glue showing that glue leads to less radiation and lower recurrence rates.

In terms of safety and associated complications, it was shown that embolization is associated only with minor complications and no reported life threatening adverse events. Fever, epididymo-orchitis, testicular or groin swelling or hydrocele were relatively common complications ranging between 0.3 and 1.9%. Spermatic vein rupture was reported with an incidence ranging between 0.3 and 5.8% with no need for reintervention having been reported. Allergic reactions during the procedure were also uncommon with an incidence of less than 1%. Non-target embolization, which is considered to be the most dreaded complication, was only reported in one case. Overall embolization-related complications were reported in less than 2% of the cases with only exception, the use of glue, which was associated with significantly higher incidence of complications such as spermatic vein rupture and perioperative pain.

In our study, it was not possible to compare pregnancy rates or sperm quality improvement, since various measures and outcomes were reported, however, majority of the study that reported outcomes on fertility reported positive outcomes. Similar were the findings regarding pain post-procedure. Once again, the studies that assessed the effect of the procedure on pain in the short- and long-run showed positive outcomes without though being able to detect a benefit from a particular embolic material, which was also the case for fertility outcomes. Cost-effectiveness was another important factor when considering treatment options and given the different costs of the various embolic material and their similar effectiveness, it can be the factor that would affect the final decision. Despite the lack of reported cost-effectiveness data, it was evident in our analysis that the addition of sclerosants in the embolization with coils does not appear to improve recurrence rates when at the same time, it is obviously increasing the cost and length of the procedure with an obvious impact on radiation exposure levels.

There are a number of significant limitations in this systematic review. The review includes studies of both adult and adolescent population and the comparisons were made indistinctively. In

addition, the majority of the studies were retrospective with small sample sizes. There was considerable heterogeneity in accessing many of the outcomes such as fertility and pain relief scales as well as cost-effectiveness. Finally, publication bias is also a possible limitation that could have an effect on the results of this study.

CONCLUSION

Percutaneous embolization for testicular varicoceles appears to be a safe procedure with a high technical success rate. At 1 year, glue appears to be the most effective in preventing recurrence with coils being the second most effective. There were no other significant differences in terms of effectiveness and safety

between the various embolic materials with only glue being associated with a higher incidence of pain and spermatic vein extravasation but without the need for reinterventions. In addition, our review showed that the addition of sclerosants in the embolization with coils are not adding on the effectiveness, whereas it is more likely to increase the cost and duration of the procedure. However, due to the significant heterogeneity between the studies and the small sample sizes, no solid conclusion can be reached and further research is warranted to assess the cost-effectiveness difference between the various embolic materials and their exact effectiveness in terms of fertility and pain control in the long-run.

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