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Vasectomy surgical techniques: a systematic review

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Abstract

Background: A wide variety of surgical techniques are used to perform vasectomy. The purpose of this systematic review was to assess if any surgical techniques to isolate or occlude the vas are associated with better outcomes in terms of occlusive and contraceptive effectiveness, and complications.

Methods: We searched MEDLINE (1966-June 2003), EMBASE (1980-June 2003), reference lists of retrieved articles, urology textbooks, and our own files looking for studies comparing two or more vasectomy surgical techniques and reporting on effectiveness and complications. From 2,058 titles or abstracts, two independent reviewers identified 224 as potentially relevant. Full reports of 219 articles were retrieved and final selection was made by the same two independent reviewers using the same criteria as for the initial selection. Discrepancies were resolved by involving a third reviewer. Data were extracted and methodological quality of selected studies was assessed by two independent reviewers. Studies were divided in broad categories (isolation, occlusion, and combined isolation and occlusion techniques) and sub-categories of specific surgical techniques performed. Qualitative analyses and syntheses were done.

Results: Of 31 comparative studies (37 articles), only four were randomized clinical trials, most studies were observational and retrospective. Overall methodological quality was low. From nine studies on vas isolation, there is good evidence that the no-scalpel vasectomy approach decreases the risk of surgical complications, namely hematoma/bleeding and infection, compared with incisional techniques. Five comparative studies including one high quality randomized clinical trial provided good evidence that fascial interposition (FI) increases the occlusive effectiveness of ligation and excision. Results of 11 comparative studies suggest that FI with cautery of the vas lumen provides the highest level of occlusive effectiveness, even when leaving the testicular end open. Otherwise, firm evidence to support any occlusion technique in terms of increased effectiveness or decreased risk of complications is lacking.

Conclusions: Current evidence supports no-scalpel vasectomy as the safest surgical approach to isolate the vas when performing vasectomy. Adding FI increases effectiveness beyond ligation and excision alone. Occlusive effectiveness appears to be further improved by combining FI with cautery. Methodologically sound prospective controlled studies should be conducted to evaluate specific occlusion techniques further.

Background

Vasectomy is performed in two distinct steps: delivering and exposing the vas deferens out of the scrotum (isolation), and occluding the vas. To isolate the vas, the use of the no-scalpel vasectomy (NSV) technique [1] is increasing among physicians who perform vasectomy in the United States [2] and in developing countries [1,3-6]. NSV proponents claim the technique leads to fewer hematomas, less bleeding, fewer infections, shorter operating times, less pain, and an enhanced acceptance of vasectomy [1]. On the other hand, others believe that NSV does not reduce the risk of surgical complications over the standard incisional approach to expose the vas [7].

Various surgical approaches to occlude the vas have been recommended over the years. Ligation with suture material and excision of a small vas segment is believed to be the most common method used world-wide [8]. According to the most recently available data, about 18% of vasectomies performed in the United States are performed by ligation with suture or metal clips [2,8,9]. Although it is the simplest method, it is considered to be the least effective [10]. Other methods have been recommended to increase the effectiveness of occlusion such as cautery of the vas lumen, interposing fascial tissue between the segments of the severed vas (know as fascial interposition (FI)), folding back of one or both vas segments onto itself, excision of a long vas segment, or a combination of two or more of the preceding techniques. Cautery combined with FI, which is believed by some to be the most effective occlusion technique [11,12], has been adopted increasingly in recent years by physicians who perform vasectomy in the United States [2]. Some authors have suggested leaving the testicular end of the vas unoccluded (known as open-end vasectomy) as a way to reduce the occurrence of post-vasectomy orchi-epidydimitis and painful granuloma [13-15].

Claims of superiority of one occlusion technique over another have been challenged by some authors [2,16,17]. They argue that the quality of data available precludes firm evidence-based conclusions about comparative effectiveness and safety of different vasectomy techniques. In view of both the apparent lack of high quality information and of existing controversies about the best vasectomy surgical techniques, we conducted a systematic review to appraise the available evidence.

The main objective of this systematic review was to assess if any surgical vasectomy technique is associated with better outcomes in terms of occlusive and contraceptive effectiveness, and complications. The following questions were considered:

1. Is NSV associated with a lower risk of surgical complications compared with the standard incisional technique?

2. Is any single occlusion method associated with a higher occlusive and/or contraceptive effectiveness compared with any other occlusion method?

3. Is any single occlusion method associated with a lower risk of complications compared with any other occlusion method?

Methods

Search strategy

We first performed a MEDLINE search (PubMed, 1966-June 2003)[18] using the terms « Vasectomy » [MESH], "Human", and "Male". We then added the terms "review" and "not review" to sort reviews and original research articles. The search strategy is described in Table 1. A similar search using the same strategy was then done with EMBASE (Excerpta Medica online, 1980-June 2003)[19]. No language restriction was applied, as at least one member of the research team was fluent in English, French or Spanish. We also looked at additional references in urology textbooks, the authors' personal files, and the references of all original research articles and relevant review articles retrieved.

Study selection criteria and procedures

Two independent members of the research team (CD and KSt-H) reviewed all titles and available abstracts identified through the MEDLINE search. We identified all articles potentially reporting: 1) a study comparing occlusive effectiveness based on semen analysis (SA), contraceptive effectiveness based on pregnancy, or post-vasectomy complications in two or more groups of men vasectomized with any different surgical techniques, or 2) two or more case series of vasectomized men published by the same author(s) using any different surgical techniques. We excluded: 1) non comparative studies (case series with no control group), 2) studies comparing a vasectomy surgical technique to a non-vasectomy vas occlusion method including intravasal devices or compounds, and 3) studies evaluating long-term post-vasectomy complications such as cancer, cardiovascular disease, and auto-immune disease or non-clinical physiopathological outcomes.

At this step, these *a priori* inclusion and exclusion criteria were loosely applied to maximize sensitivity over specificity. Reviewers agreed on potential relevance in 92% of the 1,575 titles and abstracts identified (Kappa 0.53, 95% confidence interval (CI) 0.48–0.56). Disagreement was resolved by discussion involving a third reviewer (ML) and we finally identified 201 potentially relevant articles. Among the 473 potentially relevant articles found in EMBASE, only 13 were not also found in MEDLINE. We

Table 1: Search strategy on MEDLINE and EMBASE

Set	Search Term
#1	"vasectomy" [MESH]
#2	Human
#3	Male
#4	#1 AND #2 AND #3 NOT review
#5	#1 AND #2 AND #3 AND review

also identified eight potentially relevant articles through hand-searching references of retrieved articles and two more in personal files.

Following the initial selection process, full reports of 219 of the 224 articles were retrieved; five articles from Chinese journals could not be obtained. Two articles in Danish were translated. Two independent reviewers, using the same inclusion and exclusion criteria reviewed all articles again. Reviewers agreed on the selection of 95% of the 219 articles (Kappa 0.80, 95% CI 0.67–0.83). Disagreement was resolved by discussion involving a third reviewer. We finally included a total of 37 research articles in our review, identified through MEDLINE (n = 29), EMBASE (n = 4), references of retrieved articles (n = 2), and personal files (n = 2).

Data extraction

For each study, two reviewers extracted independently the research design, eligibility criteria, sample size, setting, study period, type and number of surgeons, isolation method, occlusion method, length and method of follow-up, outcome measures (occlusive and contraceptive failure and/or complications), data collection process, and results using a data extraction grid. Discrepancies were discussed and resolved by consensus involving a third reviewer. Studies were unmasked for authors and journals. We attempted to contact the authors of some studies in order to clarify key methodological elements or results.

Quality assessment of studies

Quality assessment of studies was carried out based on study design, sample size, comparability of study groups, effectiveness and complication assessment methodology, and follow-up/compliance rate (Table 2, Additional file 1). No global quality score was calculated but a level qualifying the methodology (five levels ranging from very low to very high) was attributed to each study based on the criteria described in Table 2. Two independent reviewers assessed the studies. Discrepancies were discussed and resolved by consensus.

Data synthesis

Studies were grouped in three broad categories: isolation, occlusion, and combined isolation and occlusion techniques. Within each category, studies were further divided into sub-categories according to specific surgical techniques, and evidence tables were created (Tables 3 to 30. Additional file 2 to 8). Only qualitative synthesis was performed within each sub-category because of heterogeneity between the studies in study design, intervention and outcome assessment. Occlusive and contraceptive effectiveness are presented as the proportion (risk) of vasectomized men reported to have a failure either based on SA (occlusive failure) or pregnancy (contraceptive failure). Within each sub-category, qualitative sensitivity analyses were performed according to these variables, and quality assessment of the methodology was carried out.

Results

A total of 31 comparative studies reported in 37 articles met the inclusion criteria. This included 10 case series published by the same authors or group of authors (some as parts of previous published results) that were considered as four comparative studies with historical controls and then combined for this review: Schmidt *et al.* [20-22], Esho *et al.* [23,24], De Los Rios *et al.* [25,26], and Moss [14,27,28]. In 13 research articles [14,15,20,26,27,29-36], multiple techniques were compared, therefore description of these articles may appear in more than one of the following sections.

Surgical techniques to isolate the vas out of the scrotum

No scalpel approach to the vas – NSV

We found nine studies comparing NSV to an incisional technique. These studies are described in Tables 3 to 6 (Additional file 2). There were two randomized clinical trials (RCT): one was a large international multicenter study of high methodological quality [37]; the other was a small study of moderate quality [38]. A non-randomized parallel controlled trial was also of moderate quality [5]. All other studies were observational and of low or very low quality [7,25,26,39-42].

The incisional techniques were not uniform across the studies (Table 3, Additional file 2); single midline incision was used in two studies [5,7] and two lateral incisions were used in three others [25,26,38,42]. The incisional technique was a mix of single and double incision in one RCT [37] and was unspecified in three observational studies [39-41]. The occlusion technique also varied among studies. However, in the five studies where it was described, the occlusion technique was similar in both the NSV and incisional groups.

Outcomes assessed, timing of assessment and measurement tools used to evaluate outcomes varied among studies (Table 4, Additional file 2). Most evaluated bleeding and/or hematoma [5,7,25,26,37-39,41,42], infection [5,7,25,26,37,38,41,42], and post-vasectomy pain [25,26,37-41]. Time to recovery, granuloma, long-term adverse events, and hospitalization were measured in some studies. With the exception of one retrospective study [7], none explicitly described the criteria used to assess the main outcome measures (bleeding/hematoma, infection, and pain).

A wide range in the risk of bleeding and/or hematoma was observed across studies, probably due to the various (undefined) criteria used: 0.3% to 17% with the NSV approach and 0.3% to 18% with the incisional techniques (Table 6, Additional file 2). However, five studies [5,37-39,42] found a lower risk of bleeding and/or hematoma with NSV, one found fewer hematoma but more bleeding [41], and two observed a similar risk [7,25,26]. Moreover, the three best quality studies – two of moderate [5,38] and one of high quality [37] – showed a clinically and statistically significant difference in favor of NSV.

The risk of infection also varied widely from 0.15% to 7.1% with the NSV approach and from 0.7% to 18% with the incisional techniques (Table 6, Additional file 2). Six studies [5,25,26,37,38,41,42] found a lower risk of infection with NSV and one observed a similar risk between the two techniques [7]. Again, the three best quality studies [5,37,38] showed a clinically and statistically significant difference in favor of NSV.

Reporting of pain was very heterogeneous including average number of days with pain and discomfort [40], frequency with pain at rest and during activity [41], and frequency according to pain intensity [37] (Table 6, Additional file 2). Overall, NSV was associated with less pain in three studies [37,40,41] and with the same level of pain in three others [25,26,38,39]. Frequency of long-term pain and of hospitalization for adverse events was similar with both approaches [37].

Overall, current available studies provide very good evidence that compared with incisional techniques the NSV approach to the vas is associated with a lower risk of surgical complications, namely bleeding and/or hematomas and infections.

Other surgical approaches to isolate the vas

We found three single articles describing other approaches to expose the vas: two lateral incisions compared with a single incision [43], a 'pin-hole' approach using a special instrument permitting vas isolation through a small stab compared with an incisional technique [29], and an electro-cautery approach (the 'electro-cautery no-scalpel vasectomy') compared with an incisional technique [3] (Tables 3 to 6, Additional file 2). The quality of the evidence from these studies is insufficient to draw any conclusion about the comparative effectiveness of any of these techniques to reduce complications.

Surgical techniques to occlude the vas

Vas ligation using suture material compared with metal clips

We found four studies comparing ligation with suture material and metals clips. These studies are described in Tables 7 to 10, Additional file 3. Two were very small studies of moderate quality: a RCT [30] and a quasi-randomized clinical trial [31]. The others were of low quality, one before-and-after trial [35] and one observational study [44].

To isolate the vas, surgeons performed one midline opening in two studies [30,31] and two lateral openings in one study [44]. The isolation method was not described in the other study [35]. Various suture materials were used: silk [30,31], cotton [44], and catgut [35]. In addition, folding back of the vas was used as well as the sutures in two studies [30,31]. Two [30,31] or four [35] clips were applied per vas. The number was not specified in one study [44].

All studies evaluated occlusive effectiveness (Table 10, Additional file 3). Two studies also assessed contraceptive effectiveness. The combined occlusive and contraceptive failure risk varied from 0% to 2.6% with clips and from 0% to 6.5% with suture material. However, three studies found similar failure risk with suture material and clips [30,31,44] and one found significantly higher failure risk with suture material [35].

Hematoma, infection and epididymitis were assessed in three studies [30,31,44], granuloma in two [30,44] and pain in one [30] (Table 10, Additional file 3). No complications were described in one study [35]. Risk of hematoma varied from 0% to 1.2% and 0% to 2%, infection from 0% to 2.6% and 0% to 8%, and epididymitis from 0% to 2% and 0% to 4% with clips and suture material, respectively.

Considering the overall results and the methodological quality of the retrieved studies, metal clips did not increase effectiveness or reduce complications when compared with any of the suture materials used.

Vas ligation using two versus four metal clips

One very low quality observational study found lower occlusive failure risk with four clips per vas than with two [27] (Tables 7 to 10, Additional file 3). No complications were reported with four clips and no data were available for the group with two clips.

Vasectomy techniques with and without folding back

We found five studies comparing vas occlusion with and without folding back (FB) (Tables 11 to 14, Additional file 4). Three trials were of moderate quality [30-32] and two observational studies were of very low quality [25,26,36].

Three studies used one midline opening to isolate the vas [30,31,36], one used NSV [32] and one used two lateral openings for the group without FB, and NSV for the group with FB [25,26]. Silk suture was used for FB in four studies: on the testicular end (identified as 'distal') in three [30,31,36] and on the prostatic end in one [32]. Ligation with two tantalum clips [30,31] or with suture material [32,36] was used in the comparison groups. One [25,26] used various suture materials in the two groups.

Occlusive effectiveness was evaluated in all studies (Table 14, Additional file 4). Two studies also assessed pregnancy risk [30,32]. Risk of occlusive failure varied from 0% to 29.1% without FB and from 0% to 3.7% with FB and risk of contraceptive failure from 0% to 0.5% without FB and 0% to 1.1% with FB. Two studies found a similar risk of occlusive failure between the two techniques compared [30,31]; two found fewer occlusive failures [25,26,36] and one found more occlusive and contraceptive failures with FB [32].

Complications assessed included hematoma or bleeding, [30-32] infection, [30-32], epididymitis [30-32], granuloma [30], and pain [30,31] (Table 14, Additional file 4). The only cases of hematoma and bleeding reported occurred with FB with a risk that varied from 0% to 2%. Risk of infection was 0% to 2.6% without FB and 0% to 8% with FB and that of epididymitis was 0% to 2% without FB and 0% to 4% with FB.

Considering the overall results and the methodological quality of the retrieved studies, there was no clear advantage of folding back either in terms of increasing effectiveness or reducing complications.

Vasectomy techniques with and without FI

Five studies comparing vas occlusion techniques with FI versus without FI were retrieved (Tables 15 to 18, Additional file 5). One reported results of a large international multicenter RCT of high methodological quality [45]. One was a non-randomized parallel clinical trial of moderate quality [32] and the other three were observational studies of very low quality [20,25,26,46].

To isolate the vas, two lateral openings were used in two studies [20,46], NSV was used in two [32,45], and both were used in one [25,26]. Although the specifics of the occlusion techniques performed differed from one study to another, all used some form of ligation and excision, with the exception of one study where the vas was only transected [46]. Within each study, the only difference in the occlusion method between the compared groups was use of FI in one group and not in the other. In one study the prostatic end of the vas was contained inside the sheath and the testicular end outside (FI on prostatic end) [20], in others it was the reverse (FI on testicular end) [32,45]; it was not clear in the remaining studies on which end FI was performed [25,26,46].

Occlusive [20,25,26,32,45,46] and contraceptive [32] effectiveness were assessed. (Table 18, Additional file 5). A wide range of occlusive failure risks were reported, varying from 1.4% to 29.1% without FI, and 0% to 16.7% with FI. The wide ranges reported are probably due in part to the differing definitions of success and failure among the studies. The best high-quality study [45] and one observational study [25,26] found significantly less occlusive failure when FI was used. Similar results were found in one of the other studies [20]. One study reported no benefit with use of FI [46] and the remaining study [32] found fewer occlusive failures with FI when open-end vasectomy was performed and more occlusive and contraceptive failures associated with FI when ligation and excision was used. Mainly based on one large randomized trial [45], there is good evidence that FI reduces the risk occlusive failure of vasectomy performed with ligation and excision.

Data on complications are limited. No clinically or statistically significant differences were associated with FI in the large randomized trial but assessment of complications was neither blinded nor based on standardized objective criteria [45].

Vas occlusion using ligation compared with cautery

We found eleven studies (17 articles) comparing ligation with cautery (Tables 19 to 22, Additional file 6). There were two moderate quality studies: a non-randomized parallel clinical trial [32] and a case series with concurrent controls [34]. Others, all of low or very low quality,

included a before-and-after trial [35], a prospective cohort study [15], and retrospective observational studies [14,20-28,33,36,47].

There was an immense degree of heterogeneity among the studies in terms of both isolation and occlusion methods used. In many studies it was not possible to determine all the specific components of the occlusion techniques used. Both NSV and incisional techniques were used to isolate the vas. Ligation was performed with various numbers of clips or diverse types of suture materials. In most cases, a segment of the vas was excised. Thermal ('hot-wire') or electro-cautery was performed on either the testicular or prostatic end, or on both. In addition, FI with suture or clips on either the testicular or prostatic end was used in conjunction with ligation or cautery in many cases. Finally, some studies left the testicular end open. Details about the specific techniques in each study are described in Table 19, Additional file 6.

Occlusive effectiveness was evaluated in all studies (Table 22, Additional file 6). Occlusive failure risks ranged from 0.4% to 29.1% with ligation and 0% to 4.8% with cautery. The results of the two moderate quality studies are conflicting. In one study [32], the combined occlusive and contraceptive failure risk over two years of follow-up was higher with cautery compared with ligation (5.9% versus 1.9%). A large degree of variability in failures was seen among the different study centers and cautery techniques used (thermal and electro-cautery). In the other study [34], with a much larger sample size, cautery was reported to be much more significantly effective with regards to occlusion than ligation with clips (0.3% versus 8.7%). Among the remaining nine, all low or very low quality studies, six found fewer occlusive failures with cautery [14,20-28,33,36], two found more occlusive failure [15,35], and one showed no difference between the techniques studied [47]. Pregnancy data were reported in four studies; however numbers were very small with no clinically significant differences between the techniques [32,33,35,47].

FI was used with cautery in six of the eleven studies [14,20-24,27,28,33,34,36]. In all of these studies, reported occlusive failure risk with cautery and FI was very small, ranging from 0% to 1.2% (0.3% or less in five of the six studies), and much lower than that observed with ligation (0.7% to 8.7%). Additionally, considering only the cautery groups of the eleven studies, occlusive failure risk in the six studies with FI was lower than in the five studies where FI was not used [15,25,26,32,35,47].

Four studies [14,15,27,28,33,34] used thermal cautery, five [23-26,35,36,47] used electro-cautery and two [20-22,32] used both cautery techniques. There were no apparent differences in the ranges of failure risk between the two kinds of cautery.

Complications assessed varied among studies and included hematoma [14,20-24,27,28,32-34], infection [14,20-24,27,28,32-34], granuloma [20-24,33,34], orchiepididymitis [20-24,32-34], and pain [33,34] (Table 22, Additional file 6). With the exception of one retrospective study [33], none of the studies explicitly described the criteria used to assess their main complication outcome measures. For all complications, the results were very heterogeneous across the studies. There was no clear increase or decrease in the risk of complications using any of the techniques with cautery or ligation.

Keeping in mind the heterogeneity in study design and methodological quality, techniques used, outcomes assessed and results, it is difficult to draw firm conclusions in terms of effectiveness and complications with regards to cautery versus ligation. However data suggest that cautery, when used with FI, is associated with a lower risk of occlusive failure compared with ligation. The data are insufficient to determine whether or not use of cautery without FI leads to better occlusive effectiveness compared with ligation and excision. We did not find any comparative studies of cautery with FI versus without FI.

Vas occlusion using thermal versus electro-cautery

There was only one study, a non-randomized trial of moderate quality [32], comparing thermal cautery with electro-cautery. A higher, although not significant, occlusive failure risk was found with electro-cautery compared with thermal cautery (Tables 19 to 22, Additional file 6). Based on this study and those reviewed in the previous section, no firm conclusions can be made about any benefit of thermal versus electro-cautery.

Techniques with and without leaving the testicular end open (open-end vasectomy)

Seven studies comparing vas occlusion techniques with and without leaving the testicular end open were found (Tables 23 to 26, Additional file 7). Two were of moderate quality: a non-randomized parallel clinical trial [32] and a case series with concurrent controls [34]. The remaining five observational studies were of low or very low methodological quality [13-15,33,48].

Isolation of the vas was incisional in two studies [13,48], NSV in three [32-34] and mixed incisional and NSV in one study [14]. A variety of occlusion methods were used for both the closed-end and open-end vasectomy groups within and between studies (Table 23, Additional file 7). Four of the seven studies used cautery and FI in combination with open-end vasectomy [13,14,33,34]. There were only two studies where open-end was the only difference

in occlusion technique between the open- and closed-end groups [13,14].

Occlusive effectiveness was assessed in all studies (Table 26, Additional file 7). Occlusive failure risk ranged from 0.02% to 50% with open-end and from 0% to 8.7% when the testicular end was closed. Two studies reported more failures with open-end than with closed-end [15,48]. One of these studies, reporting a 50% failure rate with open-end vasectomy, included only four men in the open-end group [48]. FI was not used in either of these studies. Three studies observed a similar risk of failure [13,14,32]. Two used cautery and FI in combination with open-end; they were the studies where open-end was the only occlusion technique difference between the compared groups [13,14]. In the other study, where FI was used in some cases but not in others in combination with open-end, almost all failures occurred when FI was not performed [32]. The remaining two studies found lower risk of failure with open-versus closed-end [33,34]. In these two studies, open-end was combined with FI and cautery. Ligation with clips was used for the closed-end technique. Pregnancy data were reported in three studies, however numbers were very small with no clinically significant differences between the techniques [14,32,33].

Assessed complications included bleeding/hematoma and infection [14,32-34], granuloma [14,15,33,34], epididymitis [13-15], [32-34] and pain [15,33,34] (Table 26, Additional file 7). In three of the four studies that reported surgical complications (hematoma/bleeding and infection) risk was slightly higher for open-end vasectomy, however the occlusion techniques in the open- and closed-end groups were not comparable [32-34]. Risk was similar between open- and closed-ended vasectomy in the other study [14].

Granulomas, identified by palpation, were observed in 97% of men with open-end and in 4% of men with closed-end vasectomy [15]. Three studies reported on the risk of painful granulomas, ranging from 0.8% to 1.5% for open-end and 0.8% to 3.2% for closed-end. The one study where open-end was the only difference in occlusion technique between the compared groups – otherwise of low quality – found a significantly lower risk with open-ended vasectomy (1.5% versus 3.2%) [13]. More painful granulomas were reported with open-end vasectomy in one study [33] and the risk was similar in the other [34].

Risk of epididymitis, reported in six studies, varied from 0% to 4% with open-end and from 0.1% to 6% with closed-end. The risk was lower with open-end vasectomy in the two studies where it was the only difference in occlusion technique between the compared groups [13,14]. More cases of epididymitis were reported with open-end vasectomy in one study [33], risk was similar in another [34] and the numbers were too small to interpret in the remaining two [15,32].

Pain with no other diagnosis was higher with closed-end in one study [33] and similar in open- and closed-end in another study [34].

Overall, results from the available studies suggest that the open-end technique is not associated with an increase in vasectomy occlusive failure risk when the prostatic end is adequately closed by mean of FI and cautery. No firm conclusions can be made about the potential benefit of the open-end technique in decreasing the risk of painful granuloma and epididymitis after vasectomy.

Surgical techniques combining isolation and occlusion of the vas (percutaneous techniques)

Only three studies describing combined vas isolation and occlusion techniques were retrieved (Tables 27 to 30, Additional file 8). Two studies compared percutaneous ligation with ligation following a traditional incisional approach [29,49] and the other compared a percutaneous electro-cautery approach to intraluminal cautery with an incisional technique [3]. The quality of evidence from these three studies is insufficient to draw firm conclusions on effectiveness and safety of these approaches, although neither appears probable.

Discussion

The aim of this systematic review was to identify the best vasectomy surgical techniques in terms of effectiveness and safety. We identified many studies comparing various vasectomy surgical techniques and we divided them into sub-categories based on the technique used. For many reasons, we were unable to perform a meta-analysis of the results and it was even difficult to compare the findings in a qualitative synthesis. Firstly, many sub-categories included only a few studies and six included only one study. Secondly, there was much heterogeneity among the studies in each sub-category with respect to setting and population studied. Most importantly, there was too much heterogeneity with regard to study design, specific surgical technique performed, and outcome assessment.

Although all studies analyzed were comparative, we did not limit our review to experimental prospective studies (trials) in order to provide a comprehensive overview of the literature on vasectomy surgical techniques. Furthermore, based on our prior knowledge of the literature, we suspected that there would be very few trials on vasectomy surgical techniques. Indeed, we found only four RCTs, with no more than two evaluating the same technique, namely NSV. In most sub-categories, there was much het-

erogeneity in study design with the majority of the reports retrieved being retrospective observational studies.

Within most sub-categories, the surgery performed was a mix of various technical components resulting in significant variation among the studies. For example, folding back (FB) was performed with either clips or sutures on the prostatic or the testicular end. Cautery was performed either with or without fascial interposition (FI) on the prostatic or the testicular end, and various lengths of vas segment were excised or cauterized either by electro- or thermal cautery, in addition to leaving or not leaving the testicular end open. These variations make it difficult to isolate the contribution to overall effectiveness and safety of a specific component of the vasectomy technique.

Evaluation of vasectomy effectiveness was based on the results of semen analysis (SA) in all studies. Data on actual contraceptive effectiveness based on pregnancy results were very scarce. Although pregnancy data would be the best endpoint to evaluate vasectomy effectiveness, SA is a good surrogate measure for pregnancy risk. Pregnancies are very rarely reported when SA shows azoospermia or only rare non motile sperm [50-53]. Very few studies specified the operational criteria used to define occlusive failure (or success) namely the number of SA, the sperm count cut-off, the motility status, and the time interval between vasectomy and last SA to establish failure (or success). The laboratory methodology and criteria used when performing SA were also rarely mentioned. It is clear from the few studies where operational definitions of occlusive effectiveness were included, that the criteria used differ from one study to the other. Nevertheless, results on occlusive effectiveness appear to be much more valid than those on safety outcomes. In most studies, assessment of post-vasectomy complications was based on unsystematic, self-referred, unblinded medical consultations with no objective criteria and no timing and length of follow-up specified. All the preceding pitfalls contribute to the overall low methodological quality of most currently available comparative studies on vasectomy occlusion techniques.

Our review has some limitations. Firstly, as mentioned earlier, most studies analysed were retrospective observational studies including case series published by the same author(s) using different techniques. Results based on case series compared with historical controls – either reported in the same or in different papers – must be interpreted with caution. In such studies, increased experience of surgeons and variations in patients' characteristics, data collection process, and outcome assessment over time are sources of potential bias. This limitation adds to the fact that in many studies the sample size was small and there was a lack of detailed information on several key methodological elements.

Secondly, it is possible that despite our rigorous process of searching and selecting articles, we have overlooked some relevant comparative studies. However, for many years, two of us (ML and MAB) have been independently surveying the literature for vasectomy studies and our own database reviewed after performing MEDLINE and EMBASE searches revealed only two studies [36,45], one not yet published at the time the computerized searches were performed. On the other hand, some potentially relevant articles from Chinese journals could not be retrieved despite many attempts, although none appeared to be a RCT based on the title or abstract in English when available. Although we did not formally ascertain publication bias, it is unlikely that a large RCT on a specific technique would have been unpublished.

Thirdly, the sets of criteria and scales we used to extract the data from the studies and to assess the quality of the methodology were not validated. However, our quality assessment criteria were largely based on the CONSORT guidelines for quality assessment of published RCT [54], they were established before the review was initiated, and were applied by independent reviewers.

Our aim was to answer three questions based on the best evidence from published reports keeping in mind the methodological limitations of the available studies.

Is NSV associated with a lower risk of surgical complications compared with the standard incisional technique?

We found good evidence that NSV is associated with a clinically significant lower risk of surgical complications, namely hematoma/bleeding and infection, compared with approaches involving one or two sutured scrotal incisions. NSV should be the preferred approach to isolate and expose the vas when performing vasectomy.

Is any occlusion method more effective in terms of occlusion and contraception compared with any other occlusion method?

Among the various vas occlusion methods reviewed, there is no evidence that, when a small vas segment is excised, ligating the vas with metal clips or folding back and suturing a vas segment over itself results in higher occlusive effectiveness than simply ligating the vas with suture material. On the other hand, there is good evidence, mainly based on a single high quality RCT, that FI increases vasectomy occlusive effectiveness when ligation with suture material and excision of a small vas segment is performed.

Evidence from the comparative studies available on cautery is not conclusive but data suggest strongly that cautery combined with FI provides the highest level of occlusive effectiveness. Even with the large heterogeneity between studies, the risks of occlusive failure reported with cautery are systematically much lower than those reported with any other occlusion methods. The higher failure risk with cautery observed in the single moderate-quality study [32] may result from putting silk sutures on the cauterized vas segments. Suturing the vas over a cauterized segment may cause necrosis and sloughing off of the segment distal to the suture and shortening of the length of the intraluminal scar. There are insufficient data to draw conclusions about the use of thermal cautery versus electro-cautery. Apart from the single comparative study included in this review, which did not show a statistically significant difference between the techniques [32], we are aware of only one other small study comparing both cautery methods [55]. The authors found better sealing of the vas after thermal cautery based on histologic studies showing fewer cases of vasitis nodasa and spermatic granuloma afterwards.

Other recent study results are consistent with our findings on cautery. In a very large non-comparative case series of 45,000 vasectomies performed with electro-cautery without FI at the Marie Stopes vasectomy centers in the UK, the observed occlusive failure risk was 0.6%, a figure comparable to that reported in most of the major comparative studies available, and the risk of contraceptive failure was 0.03% [56]. Family Health International, NC, USA and EngenderHealth have just completed a prospective observational study of vasectomy performed with cautery (D Sokal, personal communication). When occlusive failure was defined as >10 million sperm/mL at 12 weeks the risk of early failures was 4/389 (1.0%). Applying the same definition of failure to the RCT on FI conducted by the same organizations [45], early occlusive failure risks with ligation and excision were 4.9% and 12.5% in the groups with and without FI, respectively.

The available data are insufficient to draw conclusions about the actual contraceptive effectiveness of any occlusion method over another. Two relevant large descriptive retrospective observational studies have been published recently. A study involving 1,052 men in Nepal showed that within three years after vasectomy 4.2% had been responsible for an unplanned pregnancy; most vasectomies were performed with ligation with suture material and excision of a small vas segment [57]. In a similar study conducted in China among 1,555 couples using vasectomy as a contraceptive method, the risk of an unplanned pregnancy varied between 4.2% after one year to 9.5% after five years [58]. There were no details on the occlusion technique used in this study.

Is any occlusion method associated with a lower risk of complications compared with any other occlusion method?

The evidence is lacking to support any one occlusion technique over others in terms of decreased risk of complications. The incidence of surgery related complications such as bleeding and/or infections does not appear to be influenced by any specific occlusion technique. Leaving the testicular end open has been hypothesized to be associated with less increase in the epidydimal pressure that may eventually lead to vas blow-outs and secondary obstruction of the epididymis, reducing the chances of vasovasostomy success [59,60]. Furthermore this approach was promoted to decrease the occurrence of post-vasectomy pain syndrome namely congestive orchi-epididymitis and painful granuloma [13-15]. Our review of comparative studies revealed insufficient evidence to prove that this is the case. However, occlusive effectiveness does not seems to be negatively affected by leaving the testicular end open when cautery and FI are combined to occlude the prostatic end of the vas.

Conclusions

Current evidence supports NSV as the safest surgical approach to isolate and expose the vas when performing vasectomy. There is also clear evidence that FI should be performed to occlude the vas when ligation and excision are used, but intraluminal cautery with FI appears to result in better occlusive effectiveness. Within the scope of our review many questions on vasectomy surgical techniques remain unresolved: 1) Is FI combined with cautery associated with a better occlusive and contraceptive efficacy than cautery or FI alone? 2) Is thermal cautery associated with a better occlusive and contraceptive efficacy than electro-cautery? 3) Is any occlusion technique associated with a lower risk of surgically complications including bleeding/hematoma and infection? 4) Is leaving the testicular end open associated with less risk of non-infectious post-vasectomy pain than occluding it? Considering that vasectomy is such a common surgical procedure in the human male, further methodologically-sound prospective controlled studies should be conducted to determine the most effective and safest vasectomy surgical techniques.

Competing interests

Two of the authors (ML and MB) are also authors of some of the articles in this review.

Authors' contributions

ML conceived and designed the study, participated in data collection and analysis, and drafted the manuscript. CD designed the study, coordinated data collection and analysis, and drafted the manuscript. MB conceived of the study, participated in data analysis and drafted the manuscript. KSt-H participated in data collection and

analysis. All authors read and approved the final manuscript.

Additional material

Additional File 1

Table 2. Criteria for study quality assessment.
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Additional File 2

Evidence tables of studies comparing approaches to isolate the vas out of the scrotum. Table 3. Characteristics of studies comparing approaches to isolate the vas out of the scrotum. Table 4 Outcome measures of studies comparing approaches to isolate the vas out of the scrotum. Table 5. Quality assessment of studies comparing approaches to isolate the vas out of the scrotum. Table 6. Complication results of studies comparing approaches to isolate the vas out of the scrotum.
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[http://www.biomedcentral.com/content/supplementary/1741-7015-2-21-S2.doc]

Additional File 3

Evidence tables of studies of vas ligation using metal clips. Table 7. Characteristics of studies of vas ligation using metal clips. Table 8. Outcome measures of studies of vas ligation using metal clips. Table 9. Quality assessment of studies of vas ligation using metal clips. Table 10. Results of studies of vas ligation using metal clips.
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Additional File 4

Evidence tables of studies comparing vas occlusion techniques with and without folding back. Table 11. Characteristics of studies comparing vas occlusion techniques with and without folding back. Table 12. Outcome measures of studies comparing vas occlusion techniques with and without folding back. Table 13 Quality assessment of studies comparing vas occlusion techniques with and without folding back. Table 14. Results of studies comparing vas occlusion techniques with and without folding back.
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Additional File 5

Evidence tables of studies comparing vas occlusion techniques with and without fascial interposition. Table 15. Characteristics of studies comparing vas occlusion techniques with and without fascial interposition. Table 16. Outcome measures of studies comparing vas occlusion techniques with and without fascial interposition. Table 17. Quality assessment of studies comparing vas occlusion techniques with and without fascial interposition. Table 18. Results of studies comparing vas occlusion techniques with and without fascial interposition.
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Additional File 6

Evidence tables of studies of vas occlusion techniques using cautery. Table 19. Characteristics of studies of vas occlusion techniques using cautery. Table 20. Outcome measures of studies of vas occlusion techniques using cautery. Table 21. Quality assessment of studies of vas occlusion techniques using cautery. Table 22. Results of studies of vas occlusion techniques using cautery.
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Additional File 7

Evidence tables of studies comparing vas occlusion techniques with and without leaving the testicular end open. Table 23. Characteristics of studies comparing vas occlusion techniques with and without leaving the testicular end open. Table 24. Outcome measures of studies comparing vas occlusion techniques with and without leaving the testicular end open. Table 25. Quality assessment of studies comparing vas occlusion techniques with and without leaving the testicular end open. Table 26. Results of studies comparing vas occlusion techniques with and without leaving the testicular end open.
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Additional File 8

Evidence tables of studies combining isolation and occlusion of the vas. Table 27. Characteristics of studies combining isolation and occlusion of the vas. Table 28. Outcome measures of studies combining isolation and occlusion of the vas. Table 29. Quality assessment of studies combining isolation and occlusion of the vas. Table 30. Results of studies combining isolation and occlusion of the vas.
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