Is Nonoperative Management the Best First-line Option for High-grade Renal trauma? A Systematic Review

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Abstract

Context: The management of high-grade (Grade IV–V) renal injuries remains controversial. There has been an increase in the use of (NOM) but limited data exists comparing outcomes with open surgical exploration.

Objective: To conduct a systematic review to determine if NOM is the best first-line option for high-grade renal trauma in terms of safety and effectiveness.

Evidence acquisition: Medline, Embase, and Cochrane Library were searched for all relevant publications, without time or language limitations. The primary harm outcome was overall mortality and the primary benefit outcome was renal preservation rate. Secondary outcomes included length of hospital stay and complication rate. Single-arm studies were included as there were few comparative studies. Only studies with more than 50 patients were included. Data were narratively synthesised in light of methodological and clinical heterogeneity. The risk of bias of each included study was assessed.

Evidence synthesis: Seven nonrandomised comparative and four single-arm studies were selected for data extraction. Seven hundred and eighty-seven patients were included from the comparative studies with 535 patients in the NOM group and 252 in the open surgical exploration group. A further 825 patients were included from single-arm studies. Results from comparative studies: overall mortality: NOM (0–3%), open surgical exploration (0–29%); renal preservation rate: NOM (84–100%), open surgical exploration (0–82%); complication rate: NOM (5–32%), open surgical exploration (10–76%). Overall mortality and renal preservation rate were significantly better in the NOM group whereas there was no statistical difference with regard to complication rate. Length of hospital stay was found to be significantly reduced in the NOM group. Patients in the open surgical exploration group were more likely to have Grade V injuries, have a lower systolic blood pressure, and higher injury severity score on admission.

Conclusions: No randomised controlled trials were identified and significant heterogeneity existed with regard to outcome reporting. However, NOM appeared to be safe and effective in a stable patient with a higher renal preservation rate, a shorter length of stay, and a comparable complication rate to open surgical exploration. Overall mortality was

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1. Introduction

The kidney is the most commonly injured genito-urinary organ and occurs in approximately 1–5% of all trauma cases [1,2]. Renal injury can be classified as blunt or penetrating according to mechanism and by grade according to the American Association for the Surgery of Trauma (AAST) organ injury severity scale (Table 1) [3]. Most cases of blunt renal trauma are low-grade injuries (Grade I–III) and can be managed conservatively [4]. There appears to be a trend towards the management of high-grade (IV–V) blunt renal trauma nonoperatively; however, strong comparative evidence is lacking in this cohort. Penetrating renal injuries have traditionally been managed with open surgical exploration, though some studies have reported favourable outcomes with nonoperative management (NOM), even in high-grade penetrating injuries [5,6].

This shift towards NOM has been driven by rapid uptake of minimally-invasive techniques such as angioembolisation, improved clinical pathways, enhanced critical care treatment for trauma patients, readily accessible computerised tomography (CT)-imaging, and a validated renal injury scoring system. Despite these advances, the optimal management of high-grade renal trauma still remains controversial with those supporting open surgical exploration reporting fewer complications [7–10], whereas advocates of NOM highlighting that conservative and minimally-invasive techniques reduce the inherent risk of nephrectomy and subsequent deterioration of renal function [11–16].

Current guidelines on the management of high-grade renal trauma are based on retrospective comparative studies and single-arm case series [17,18]. Existing reviews have not focused on high-grade injury and most were not conducted systematically [4,19,20]. A systematic review of current evidence is required to establish whether the outcomes of open surgical exploration and NOM are comparable.

The objective of this systematic review was to compare NOM which encompasses angioembolisation, ureteric stenting, and conservative management against open surgical exploration, in the management of high-grade renal injuries.

2. Evidence acquisition

The systematic review protocol was registered with PROSPERO (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016035255).

2.1. Search strategy and selection criteria

The review was performed according to Preferred Reporting Items for Systematic Reviews and Meta-analysis [21]. Studies (January 1, 1946 to June 1, 2016) were identified by highly sensitive searches of electronic databases (Medline, Medline In-process, Embase, Cochrane library databases). The initial literature search was performed on April 24, 2015 and an updated search performed on June 03, 2016. The search strategy is described in detail in the Supplementary data. Animal studies, children, case reports, and letters were excluded.

2.2. Types of study design included

There was no restriction on types of study design. Single-arm studies were included as there were only a small number of nonrandomised comparative studies. All studies required a minimum of 50 patients and there were no restrictions on language or date of publication.

2.3. Types of participants

The study population was adults (≥18 yr) with high-grade (Grade IV–V according to AAST classification) CT-confirmed blunt and penetrating injuries.

2.4. Types of intervention

The control group was open surgical exploration. The experimental group consisted of patients who received NOM...
which included conservative (supportive management only), minimally invasive intervention (angioembolisation, ureteric stent insertion, percutaneous drainage), “package of care” involving step-wise approach (ie, starting with conservative, followed by minimally invasive and/or surgical exploration if necessary).

2.5. Types of outcome measures

The primary harm outcome was mortality (overall and renal trauma-related). The primary benefit outcome was renal preservation (ie, kidney removal or complete embolisation vs preservation). Secondary outcomes included complications and length of hospital stay. Identified confounders included systolic blood pressure, injury severity score, renal function, blood loss, reintervention rate, and development of hypertension.

2.6. Data collection and data extraction

Following deduplication of abstracts, two reviewers (A.S. and P.J.E.) screened all abstracts and full-text articles independently. Disagreement was resolved by a third party (E. V.). References cited in all full-text articles were also assessed for additional relevant articles. A standardised data-extraction form was developed a priori to collect information on study design, renal injury details, patient characteristics, and outcomes measures.

2.7. Risk of bias in individual studies

Two reviewers (A.S. and P.J.E.) assessed the “risk of bias” of each included study independently. Any disagreements were resolved by discussion or by consulting a third review author.

Risk of bias in nonrandomised comparative studies was evaluated using a modified version of a recommended tool used in the Cochrane Handbook for Systematic Reviews of Interventions. This was a pragmatic approach based on methodological literature [22,23] and included an additional domain to assess the risk of confounding bias. A list of the five most important potential confounders for harm and benefit outcomes was developed a priori with clinical content experts (European Association Urology [EAU] Trauma guideline panel). The confounding factors were: type of injury (blunt/penetrating), associated injuries, haemodynamic stability of patient, patient fitness, and available interventions. This approach is detailed in our study protocol [24].

For single-arm studies, risk of attrition bias, whether an a priori protocol was available (indicating prospective design), and selective outcome reporting were assessed.

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Fig. 1 – Preferred Reporting Items for Systematic Reviews and Meta-analysis flow diagram: search and study selection process for this review. AAST = American Association for the Surgery of Trauma; CT = computerised tomography.
External validity was also addressed by assessing whether study participants were selected consecutively or representative of a wider patient population. This too is a pragmatic approach informed by methodological literature [25,26].

2.8. Statistical analysis

Meta-analysis could not be performed due to methodological and clinical heterogeneity of the included studies. Therefore, a narrative synthesis was performed instead (https://www.york.ac.uk/crd/guidance/). Forest plots of risk difference were constructed for comparative studies for three outcome measures (mortality, complications, and renal preservation). This was not done for length of stay since standard deviations were not consistently reported in the included studies. Statistical methods of assessing heterogeneity were not feasible therefore potential reasons for heterogeneity were explored in relation to population differences, outcome definitions, as well as the methods used to report outcomes. Planned formal subgroup analyses were not possible due to inclusion of nonrandomised controlled studies. Therefore, any subgroup differences were discussed narratively to explore potential effect size differences. The planned sensitivity analysis to assess the robustness of our review results, by repeating the analysis only including studies with an overall medium to low risk of bias, was also not performed due to the inclusion of nonrandomised comparative studies.

3. Evidence synthesis

3.1. Quality of the studies

A total of 1375 studies were identified by the literature search and two reviewers screened all study abstracts independently. Of these, 54 articles were selected for full-text screening and 11 studies (7 nonrandomised comparative studies, 4 single-arm studies) were eligible for inclusion (Fig. 1). The quality of studies was assessed as described above. Risk of bias is summarised for comparative studies in Fig. 2 and for single-arm studies in Fig. 3. Overall there was a high risk of bias across both comparative and single-arm studies. Study design was retrospective for all studies. Although some studies prospectively inputted data into a database, they were still retrospective in study design [27–31].

3.2. Study details

Three of the comparative studies included penetrating and blunt injuries and four only reported on blunt injuries.
All single-arm studies reported on patients who had received NOM for blunt injuries. Recruitment periods ranged from 1981 to 2015 and studies were published from 2006 to 2015. Most studies were performed at trauma centres, although three were from a general hospital [29,32,33]. Most studies were performed in a single-centre. One study was performed across two centres, another across 12, and a multi-centre study used data from 331 units (National Trauma Database Bank).

### Table 2 – Characteristics of included studies.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study design</th>
<th>Country</th>
<th>No. of centres</th>
<th>Type of centre(s)</th>
<th>Recruitment period</th>
<th>No. of patients NOM</th>
<th>No. of patients open surgical exploration</th>
<th>Blunt / penetrating</th>
<th>Outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>VanderWilden [34]</td>
<td>2013</td>
<td>Retrospective</td>
<td>USA</td>
<td>12</td>
<td>Trauma centres</td>
<td>10 yr (2000–2011)</td>
<td>154</td>
<td>52</td>
<td>Blunt only</td>
<td>Mortality, compr,comp, RP, LOS</td>
</tr>
<tr>
<td>Malaeb [38]</td>
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<td>Retrospective</td>
<td>USA</td>
<td>1</td>
<td>Trauma centre</td>
<td>8 yr (2003–2010)</td>
<td>144</td>
<td>NA</td>
<td>Blunt only</td>
<td>Mortality, RP, LOS</td>
</tr>
<tr>
<td>Sangthong [37]</td>
<td>2006</td>
<td>Retrospective</td>
<td>USA</td>
<td>331</td>
<td>Trauma centres</td>
<td>13 yr (1991–2003)</td>
<td>376</td>
<td>NA</td>
<td>Blunt only</td>
<td>Mortality</td>
</tr>
</tbody>
</table>

Comps = complications; LOS = length of stay; NA = not applicable; RP = renal preservation.

(European Urology Focus 5 (2019) 290-300)

Table 2: Characteristics of included studies.

Fig. 3 - Break of data table for single-centre studies.

- Outcome appropriately measured (outcome measurement bias)?
- Renal preservation
- Selective reporting (reporting bias)
- Incomplete outcome data (attrition bias): renal preservation
- Incomplete outcome data (attrition bias): mortality
- Total population or consecutive patients?

<table>
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<tr>
<th>Author</th>
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<th>Country</th>
<th>No. of centres</th>
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studies. One study excluded patients below 15 yr of age and those who died before arrival to the hospital. Sarani et al [36] excluded patients who had a laparotomy without preoperative CT (Tables 2 and 3).

Allocation to the different treatment groups was not randomised in any of the studies. Six studies opted for open surgical exploration if the patient was haemodynamically unstable at presentation and/or was not responding to resuscitation [28–30,32,34,35]. Other indications for open surgical exploration in these studies included peritonitis, failed embolisation, persistent bleeding, an expanding or pulsatile haematoma, and polytrauma patients in haemorrhagic shock. One study did not specify indications for open surgical exploration [36]. Three studies followed an institutional first-line NOM protocol [28,30,31] with one study explicitly stating that even unstable patients should receive angioembolisation as first line therapy [30].

Eight hundred and twenty-five patients were included from single-arm studies with blunt injuries and received NOM. Three studies included only Grade IV injuries [31,37,38] and one study included Grade III–V studies [33]. Of these studies only Long et al [31] stated the use of a first line nonoperative protocol whereby NOM, including angioembolisation in haemodynamically unstable patients, was preferred and open surgical exploration was only performed if immediate resuscitation failed. There was a lack of consistency with regard to which outcomes were reported and how they were measured in comparative and single-arm studies. Only three of the comparative studies reported on all four study outcome measures [29,32,34].

### 3.3. Outcomes

#### 3.3.1. Mortality

Five comparative studies reported on overall mortality [29,30,32,34,36] (Table 3). A significant difference in overall mortality existed in favour of NOM in two studies (Fig. 4a) [34,36]. Van der Wilden et al [34] reported three (2%) patients with renal-related deaths but did not compare rates between NOM and open surgical exploration. Buckley and McAninch [29] and Shoobridge et al [30] both reported that both deaths in the NOM group were not renal trauma–related; therefore, there was no difference found between groups in these two studies with regard to renal-trauma related mortality. Only one case series reported overall mortality and it was 21% in the NOM group [37]. No included studies reported the specific time-to-death following renal injury. Four out of the five studies that reported on overall mortality, used in-hospital mortality [30,32,34,36].

#### 3.3.2. Renal preservation

Four comparative studies provided data on renal preservation (Table 3) [28,29,32,34]. In all four studies, renal preservation rate was higher in NOM (range, 84–100%) compared with open surgical exploration (range, 0–82%) and in three of these studies there was a significant risk difference in favour of NOM (Fig. 4c).

<table>
<thead>
<tr>
<th>Table 3 – Outcomes.</th>
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<tbody>
<tr>
<td><strong>Author</strong></td>
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<tr>
<td><strong>Comparative studies</strong></td>
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<tr>
<td>Buckley [29]</td>
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<td>Elashry [32]</td>
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<td>Sarani [36]</td>
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<td>Shariat [35]</td>
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<td>Maarouf [33]</td>
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<td>Maarouf [33]</td>
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</table>

NR = not reported; OSE = open surgical exploration.
3.3.3. **Complications**

Six comparative studies provided data on complications (Table 3). In terms of absolute rates, three studies found a higher complication rate in NOM groups and three studies found patients who underwent open surgical exploration had a higher complication rate. However, only two studies reported a significant difference between groups and showed a lower rate in NOM (Fig. 4b) [30]. The three studies that reported lower complication rates in the open surgical exploration cohort showed no statistical difference compared with NOM.

Although all studies specifically reported on renal-related complications, there was a large amount of heterogeneity in their classification and reporting. Only one study used a recognised grading system (Clavien-Dindo) [30]. Common complications in the NOM group included fever, haematuria, acute kidney injury, and nonresolving urinomas requiring either ureteric stenting or percutaneous...
drainage. In the open surgical exploration group, complications included wound infection, urinary tract infection, and perinephric abscess requiring drainage.

No included studies reported on exact time to event for complications, though four out of five comparative studies [30,32,34–36] and three out of four single-arm studies [31,33,38] which reported on complications used short-term in-hospital complications.

3.3.4. Length of stay
Six studies reported on length of stay and across these studies it was longer in open surgical exploration group (24 days) compared with the NOM group (17 days) (Table 3). This was the trend in all the studies and two studies found there to be a statistically significant difference between the two interventions [32,35].

3.3.5. Confounders
Some confounders developed a priori including patient fitness and available interventions were not consistently reported in studies. Data was available on grade of injury, systolic blood pressure on admission, and Injury Severity Score (ISS) in two or more studies (Table 4). There was a higher proportion of Grade IV injuries in the NOM group and a higher proportion of Grade V injuries in the open surgical exploration group. Two studies both found the mean systolic blood pressure to be significantly lower in the open surgical exploration group than NOM group. ISS was available in two studies and was also found to be significantly higher in the open surgical exploration group than NOM group.

3.3.6. Subgroup analysis
3.3.6.1. Blunt versus penetrating. Three studies included penetrating high-grade injuries in their population cohort. One study found that three injuries were managed successfully using conservative measures and the one patient who underwent open surgical exploration survived but required a nephrectomy [30]. Two studies further divided penetrating injuries into stab and gun-shot injuries [29,35]. Both studies found that patients with gunshot injuries were the most likely to undergo surgical exploration and subsequent nephrectomy compared with stab and blunt injuries.

3.3.6.2. Isolated renal injuries. One study [29] reported on the outcomes of 43 patients who sustained isolated Grade IV renal injuries. Surgical exploration was performed in 18 of 43 patients with a renal salvage rate of 83%. The remaining 25 patients were managed nonoperatively with a renal salvage rate of 88%. Average hospital stay was similar in both groups and transfusion rates were higher in the surgical exploration group.

4. Conclusions
This is the first systematic review to use transparent and rigorous methodology to compare NOM and open surgical exploration in the management of high-grade renal trauma. In many units, first-line nonoperative protocols have been implemented ahead of acquiring objective evidence due to the difficulty in conducting adequately powered randomised controlled trials. Nonetheless, this study focuses on the best available studies with population sizes greater than 50 patients, and appraises the risk of bias in a transparent way, to assess important outcomes that may not be apparent when reviewed in isolation.

4.1. Principal findings
4.1.1. Mortality
Overall mortality was found to be worse in the open surgical exploration group compared to NOM group, albeit in three out of five comparative studies with small sample sizes and low event rates. Patients in the open surgical exploration group had higher rate of Grade V injuries, higher ISS scores, and lower systolic blood pressure values on admission. Both ISS scores and lower systolic blood pressure values on admission have been shown to be predictors of increased mortality following trauma [39,40]. Therefore, this finding, together with selection bias present in most included
studies whereby the most unstable patients underwent open surgical exploration, could explain the difference in overall mortality between both groups. There was no evidence of a difference in renal-trauma related mortality between the two interventions in two studies [29,30].

4.1.2. Complications
Included studies rarely defined and reported complications in a consistent manner. Comparisons can still be made between interventions in the same study. Although three studies reported increasing complication rates in the NOM group, these were not statistically different. Only one study showed a statistical difference and graded complications according to the Clavien–Dindo classification [30]. Given the substantial heterogeneity it is difficult to conclude that a higher complication rate exists. This is contrary to many other studies that reported a weakness of NOM to be the high frequency of short-term complications [7–9].

4.1.3. Renal preservation
Previous studies have shown that open surgical exploration can lead to higher nephrectomy rates [5,41–43]. Our data showed that 84–100% of patients had preserved renal units following NOM compared with a 0–82% renal-preservation rate following open surgical exploration. This finding confirms the greater risk of nephrectomy once a decision for open surgical exploration is undertaken.

A weakness of many studies related to renal trauma is a lack of long-term follow-up to measure residual renal function. Only one study [28] reported on relative postoperative renal function 6 mo post-trauma using dimercapto-succinic acid renal scintigraphy and found poorer long-term renal function was related to the percentage of devitalised parenchyma and associated visceral lesions. Studies comparing radical nephrectomy versus partial nephrectomy, although performed on a different population, provide an insight into the potential long-term negative impact of trauma nephrectomy. In selected patients, radical nephrectomy was shown to be associated with poorer survival and the development of chronic kidney disease compared with partial nephrectomy [44–46].

4.1.4. Comparison with current guidelines
Current guidelines recommend immediate intervention (open surgical exploration or angioembolisation) for haemodynamically unstable patients [18,27]. The American Urological Association guidelines state that angioembolisation is an option only in experienced centres and surgical exploration should be used in other units. The EAU guidelines state angioembolisation is a first-line option in patients with active bleeding and no other indications for immediate open surgery. For those who do not meet the criteria for immediate intervention, American Urological Association guidelines state that injury grade should not influence whether a patient receives surgical exploration or NOM and the EAU recommends surgical exploration only for Grade V vascular injuries. These guidelines highlight the importance of clinical as well as institutional factors (angioembolisation facilities, availability of minimally invasive techniques, and level of critical care support) in deciding on the appropriate management. The current study classified angioembolisation as a nonoperative intervention therefore directs comparisons to the guidelines are difficult. However, the benefits of a conservative approach to high-grade renal injury are evident.

4.2. Clinical implications

The ultimate goal of conservative or minimally–invasive management is to minimise unnecessary explorations and reduce iatrogenic nephrectomy rates without increasing morbidity or mortality. This study has shown that outcomes following NOM are at the very least noninferior to those following open surgical exploration, all while avoiding the morbidity associated with surgery. The findings from our study help to strengthen the argument for conservative management taking into account some of the absolute indications for surgical exploration that have been discussed.

The NOM of trauma can be viewed as a “package of care”; a step-wise approach starting with conservative, followed by minimally invasive and/or surgical exploration if necessary. It should be noted that an algorithm for “package of care” will vary in different centres according to available interventions; however, the importance of escalation in treatment interventions should be emphasised.

4.2.1. Limitations
High-powered studies on trauma are difficult to conduct due to relatively low incidence and concerns about studies in life-threatening situations. Using retrospective comparative studies is the next best approach but remains a challenge as management has already shifted to NOM in many units. It is our belief that this review provides the first rigorously conducted systematic review on high-grade renal injury and therefore represents a review of current available best evidence.

There was high risk of bias in the included studies predominantly due to the retrospective study design and selection bias. Analysis of study confounders showed that patients in the open surgical exploration group were more likely to have Grade V injuries, be more clinically unstable on admission, and have a higher ISS compared with those in the NOM group. It is important therefore that certain outcomes heavily influenced by such confounders such as overall mortality are interpreted with caution. Mortality and complication rates were not reported on a time-to-event basis in included studies which together with small sample sizes and low event rates mean findings should be also interpreted cautiously. Although most studies reported mortality and complications that occurred “in-hospital,” the lack of defined time periods is a key limitation. Included studies which reported on complications did not provide separate data for men in the open surgical exploration group who did not require nephrectomy. Subsequently, some of the complications incurred in this group could be related specifically to the nephrectomy. However, given that most patients who underwent exploration did not require nephrectomy and that the spectra of complications
with or without nephrectomy will be similar, the degree of overestimation of complications in the exploration group will be low.

High-grade renal injury conventionally encompasses Grade IV and V renal injuries according to the AAST classification. Variation may exist across institutions on whether injuries are classified as Grade IV or V dependent on reporting radiologists. Caution must be exercised when allocating a defined protocol for high-grade renal injuries when Grade IV and V injuries are grouped.

Well-designed trials comparing these two modalities are lacking and the mainstay of reports in the literature remain retrospective case-series. The comparative observational studies identified are limited by selection bias that occurs between interventions and therefore any statistical pooling of data is misleading. Furthermore, consensus is needed regarding which outcomes are reported, how they are defined, as well as how and when they are measured. This will enable more meaningful comparisons in the evidence base in future.

4.3. Conclusions

This systematic review has provided evidence that NOM is the most appropriate first-line management option in high-grade renal trauma resulting in a renal preservation rate of approximately 84–100%. This systematic review has highlighted the difficulty in comparing NOM and open surgical exploration due to inherent selection bias that will remain an issue unless consensus on outcome definition, measurement, and reporting is achieved and adopted for future studies. The use of functional tests such as dimercapto-succinic acid renal scintigraphy or blood parameters such as serum creatinine should be more often reported in comparative studies, if possible beyond 6 mo. We recommend the development of prospective multi-centre trauma registers as well as standardised reporting of outcome measures to assist in making fair comparisons between studies.

Author contributions: Arunan Sujenthiran had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Sujenthiran, Elshout, Veskimae, MacLennan, Serafetinidis, Sharma, Kitrey, Djakovic, Lumen, Kuelhas, Summerton.

Acquisition of data: Yuan.

Analysis and interpretation of data: Sujenthiran, Elshout, Veskimae.

Drafting of the manuscript: Sujenthiran.

Critical revision of the manuscript for important intellectual content: MacLennan, Serafetinidis, Sharma.

Statistical analysis: None.

Obtaining funding: None.

Administrative, technical, or material support: None.

Supervision: MacLennan, Serafetinidis, Sharma.

Other: None.

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Appendix A. Supplementary data

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References