Heparin-bonded circuits versus nonheparin-bonded circuits:
an evaluation of their effect on clinical outcomes

Omar Mangoush a,*, Sanjay Purkayastha b, Saleem Haj-Yahia c, James Kinross b,d, Martin Hayward a, Fabio Bartolozzi e, Ara Darzi b,d, Thanos Athanasiou b,d

a National Heart & Lung Institute, Imperial College of Science, Technology and Medicine, Department of Cardiothoracic Surgery, The Heart Hospital, UCLH, London, UK
b Department of Biosurgery & Surgical Technology, Imperial College of Science, Technology and Medicine, London, UK
c National Heart & Lung Institute, Imperial College of Science, Technology and Medicine, Department of Cardiothoracic Surgery, Harefield Hospital, Middlesex, UK
d National Heart & Lung Institute, Imperial College of Science, Technology and Medicine, Department of Cardiothoracic Surgery, St Mary's Hospital, London, UK
*e Department of Cardiothoracic Surgery, New Cross Hospital, Wolverhampton, UK

Summary

Heparinization of the blood contact surface in cardiopulmonary bypass circuits has been promoted as an important step in the development of open heart surgery. As it decreases the inflammatory response resulting from the extracorporeal circulation, it may have a positive effect on clinical outcomes. This meta-analysis was carried out to examine if heparin-bonded circuits (HBCs) reduce the need for blood products and improve overall clinical outcome. A systematic literature search was performed to identify randomized controlled trials reporting outcomes of HBCs compared with non-HBCs. Primary outcomes assessed were postoperative blood/blood-product transfusion and blood loss. Secondary outcomes included all-cause mortality, acute postoperative myocardial infarction, stroke, re-sternotomy for postoperative bleeding, wound infection, atrial fibrillation, duration of ventilation, intensive care unit (ICU) and hospital-length of stay (LOS). Random effects meta-analytical techniques were applied to identify differences in outcomes between the two groups. Quality of the included studies and heterogeneity were assessed. From an initial review of 762-published studies, 41-randomized trials fulfilled the inclusion criteria, leaving 3434-patients’ data for analysis. HBCs significantly decreased the incidence of blood transfusion required (OR = 0.8; 95% CI = 0.6:0.9, P = 0.004). It also significantly decreased re-sternotomy (OR = 0.6; 95% CI = 0.4:0.8, P = 0.002), duration of ventilation (WMD = −1.3 h; 95% CI = −1.9:−0.6, P < 0.001), ICU-LOS (WMD = −9.3 h; 95% CI = −14.7:−3.9, P < 0.001) and hospital-LOS (WMD = −0.5 day; 95% CI = −0.9:−0.1, P = 0.02). HBCs had no effect on other adverse events evaluated. Although HBCs showed a positive effect on some of the clinical outcomes, we identified only marginal differences for other outcomes. Further evaluation of the cost-effectiveness of this technology is required.

Keywords: Heparin-bonded circuit; Cardiopulmonary bypass; Perfusion; Meta-analysis

1. Introduction

Many improvements have been implemented into cardiopulmonary bypass circuits since the beginning of their use in early 1960s. Heparinization of the blood contact surface of the circuit has been promoted to be an important step in the development of bypass circuits. Although the anti-thrombotic property of heparin was the main factor understood when it was initially used in some medical devices [1, it has been proven to have many other biocompatibility properties as it inhibits contact activation, complement activation, and adsorbs lipoproteins which may create a surface that can potentially simulate cell membranes [2].

Heparin bonded cardiopulmonary bypass circuits (HBCs) have the potential to decrease the postoperative blood loss as well as reduce transfusion requirement of blood and blood products. Also through decreasing the inflammatory response from the utilization of extracorporeal circulation it may have positive effects on certain other clinical outcomes. Although HBCs have been tested extensively, both experimentally and clinically in the last decade, at present, very few centers use this technique routinely.

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As most of these trials have recruited small numbers of patients individually, they have often been under powered to adequately explore important effects on clinically relevant outcomes, such as death, myocardial infarction, stroke, wound infection, atrial fibrillation (AF), hospital and intensive care unit (ICU) stay. Of major concern is the availability of a large number of circuits in the market and the recruitment of different patients groups in these trials, as these may have complicated the objectivity in decision-making. Statistical aggregation of randomized trials through meta-analysis allows for increased power to detect potential differences in clinical outcomes [3,4].

The aim of the present study was to determine whether HBCs reduce mortality, morbidity, or resource utilization when compared with non-HBCs (NHBCs) through systematic review and meta-analysis of all the relevant randomized trials available in the literature at present.

2. Methods

2.1. Searching for trials

This meta-analysis of randomized trials was performed in accordance with methodological recommendations, including the quality of reporting of meta-analysis consensus statement, the Cochrane Collaboration recommendations [3,4] and according to a protocol that pre-specified outcomes, search strategies, inclusion and exclusion criteria, and statistical analyses. A search was undertaken in accordance with Cochrane Collaboration recommendations to identify all published or unpublished, English and non-English randomized trials of HBCs versus NHBCs articles were included. Medline, the Cochrane Library, Embase databases and Web of Science were searched from the date of their inception to the end of December 2004. No language restrictions were made. Search included only human studies and the following MeSH search headings were used: 'clinical trials', 'randomized controlled trials', 'random allocation', 'double-blind method', 'single-blind method', 'placebos', 'comparative study', 'evaluation studies', 'follow-up studies', 'prospective studies' and 'research design'. Search terms included variants and combination of: 'extracorporeal circuit', 'circuit brand names', 'heparin coated' and 'coronary artery bypass'. Tangential electronic exploration of related articles and hand searching of the bibliography, scientific meeting abstracts, and related journals were also performed.

2.2. Inclusion criteria

Studies were included if they met each of the following conditions: (1) Randomized allocation to HBCs versus NHBCs. (2) Involved open heart surgery. (3) Reporting at least one pertinent clinical outcome. Blinded and non-blinded studies were included.

2.3. Exclusion criteria

Studies were excluded from the review if: (1) The trial recruited congenital heart disease or transplantation patients. (2) The trial used auto-transfusion techniques to manage postoperative bleeding. (3) There was modification of the circuit in only one arm of the study, other than heparin coating of the inner surface. (4) The trial’s patient cohort had overlap with a previously published study (5) A study had published results subsequent to a previously published study (the least relevant outcome, the smallest and the oldest, were excluded). (6) A zero cell was displayed for the outcomes of interest for both groups.

2.4. Data extraction

Two reviewers independently (OM and TA) identified trials for inclusion and extracted information on demographics, interventions, and outcomes according to pre-specified protocol. Authors of included trials were contacted when necessary to clarify data and to identify multiple publications. Two reviewers independently assigned each trial a Jadad quality score [5] that evaluates randomization, blinding, and completeness of follow-up (maximum score = 5). Disagreements were resolved by consensus.

2.5. Outcomes and definitions

The primary outcomes were defined as the incidence of postoperative blood product transfusion (the number of patients who required blood transfusion), the amount of blood product transfused and blood loss. Secondary outcomes included all-cause mortality, postoperative incidence of acute myocardial infarction, stroke, re-sternotomy rates, wound infections, AF, duration of ventilation, ICU length of stay (LOS) and total hospital LOS.

Postoperative blood loss was measured 24 h postoperatively and just prior to removal of drains. Studies that documented blood loss at different postoperative time points were few, therefore, were excluded to reduce heterogeneity. Studies that documented the number of units of blood or blood-product transfusion but not the number of milliliters were converted appropriately (one unit of packed red cells (PRC) converted to 316 ml and one unit of platelets or fresh frozen plasma (FFP) converted to 300 ml). The incidence of transfusion was defined as the number of patients requiring blood (usually defined as red blood cell) transfusion during the intra-operative and postoperative period combined. When data were presented separately for the intra-operative and postoperative periods (i.e., no combined estimate was provided), the postoperative transfusion requirements were preferentially extracted to avoid counting patients’ data twice. Mortality was defined as all-cause, 30-day mortality. Acute myocardial infarction was defined per study using author definitions of new onset infarction using electrocardiogram or enzymatic criteria. Stroke was defined as neurological deficit that lasted more than 24 h during the overall hospital stay. Sternal wound infection was defined per study author definitions. AF defined by electrocardiographic criteria during hospital stay. Duration of ventilation was measured from end of surgery to the time of tracheal extubation. Intensive care LOS and hospital LOS were measured from end of surgery to ICU or hospital discharge, respectively.
2.6. Statistical analysis

Meta-analysis was performed in line with recommendations from the Cochrane Collaboration and the quality of reporting of meta-analyses (QUORUM) guidelines [3,4]. The effect measures estimated were odds ratio (OR) for dichotomous data and weighted mean difference (WMD) for continuous data, both reported with 95% confidence intervals (CI). An OR of less than one and WMD less than 0 favored HBCs group. The point estimate of the OR or WMD was considered statistically significant at the \( P < 0.05 \) level and the 95% confidence interval dose not include the value one for the OR, or zero for WMD. Combination of the OR of the outcomes of interest was performed with the Mantel–Haenszel Chi-square method [6]. Studies that contained a zero in the number of events of interest in both control and study groups resulted in problems with the computation of ratio measurement, therefore, these study outcomes were excluded. Data for the chosen outcomes were entered into Review Manager Version 4.2 (The Cochrane Collaboration, Software Update, Oxford, UK). Pooled estimates, CI and tests for heterogeneity were calculated, and visual evaluation of possible publication bias was performed by the use of funnel plots [7]. In the forest plots of the results, squares indicate point estimates of treatment effect (OR or WMD), and 95% confidence intervals indicated by horizontal bars. The diamond represents the summary estimate from the pooled studies with 95% confidence intervals.

In a ‘fixed effect’ model it is assumed that there is no heterogeneity in treatment effect between studies, whereas in a ‘random effect’ model it is assumed that there is variation between studies and the calculated odds ratios thus have a more conservative value [6,8]. With respect to the studies included in the present analysis, surgeons used different techniques and each center has its own selection criteria for the patients and these patients had different risk profiles. Therefore, the use of the random effect model was preferable for these surgical outcomes meta-analysis.

Heterogeneity was explored using the Q-statistic, but the \( I^2 \) value was calculated to quantify the degree of heterogeneity across trials that could not be attributable to chance alone. As this value indicates the proportion of variability between trials that cannot be attributable to chance alone, it provided an improved measure of heterogeneity between trials as it is independent of the number of trials included in the analysis and is not limited by power [3,9,10]. When \( I^2 \) is greater than 50, it indicates significant heterogeneity. Thus three strategies were employed to quantitatively assess heterogeneity and selection bias between the studies: (1) Data was analyzed using random and fixed effect models; (2) Graphical exploration with funnel plots was used to evaluate publication bias [7]; (3) Sensitivity analysis was undertaken for the following subgroups: (i) isolated CABG; (ii) elective surgery; (iii) high dose heparin (to keep ACT \( > 450 \)); (iv) circuit type (in particular the Carmeda circuit); (v) studies published after 1998; (vi) high quality studies (Jadad score \( \geq 3 \)); (vii) double-blind studies. These subgroups were identified in the protocol prior to conducting the review and analysis.

3. Results

Fig. 1 outlines the search results. Eighty-four studies were excluded for the following reasons: 2 non-random design [11,12], 6 involved congenital or transplantation surgery [13–18], 6 non-NHBCs group in the study [19–24], 35 no extractable data reported [25–59], 1 pooled study [60], 2 only abstract (no trial published) [61,62], 13 studies had overlap of patient cohorts with other included studies [63–75], 15 used postoperative auto-transfusion technique [76–90], and 4 had modification of circuit [77,91–93]. Of the remaining studies, we identified 41 independent randomized trials reported in 41 published papers [94–134]. Six studies had more than two arms in the same study, five studies with three arms (one NHBCs and two HBCs) [95,96,121,122,132] and one with four arms (two NHBCs and two HBCs) [123]. Five [95,96,121–123] of these studies were considered as two trials and labeled as A and B, i.e., the NHBCs arm was statistically duplicated in four trials. Therefore, a total of 3434 patients in 41 original trials provided data for this meta-analysis.

The characteristics of these studies are shown in Table 1. Thirteen studies [79,83,87,100,102,104–106,109,116,117,130,133] matched control and treatment groups for four or more criteria out of eight, which predict blood loss after open heart surgery [135,136]. Thirteen trials were double-blinded [78,80,81,87,106,110,116,128–130,132–134], seven studies used low dose heparin in HBCs group [95,96,115,116,126,129,137] and the median Jadad score was 2.7 (range, 2–5). Table 2 shows the outcome of interest documented in each study.

Statistically significant heterogeneity was found for blood loss, blood product transfusion, and ICU-LOS (Table 3). Funnel plots showed no clear evidence of publication bias for any endpoints evaluated.

3.1. Clinical outcome

Table 3 and Figs. 2–4 outline primary and secondary outcomes. There was no significant difference in the amount of postoperative blood loss between the two groups in studies
that reported 24 h blood loss. However, studies that reported blood loss at the time of drain removal showed that the blood loss was significantly reduced in HBCs group (WMD, \(0.6-0.9\), \(P = 0.001\)). Similarly, there was no significant difference in the amount of postoperative blood product transfusion. However, there was significant difference in the percentage of patients who had blood transfusion in favor of HBCs group (OR, 0.8; 95% CI, 0.6–0.9, \(P = 0.004\)). There was no significant difference in death between both groups. None of the adverse events
separately, was significantly different between the two groups, except re-sternotomy, which was reduced in HBCs group (OR, 0.6; 95% CI, 0.4—0.8, \(P = 0.002\)). There was also no significant difference in composite adverse events (death, MI, stroke, re-sternotomy, wound infection and AF). The duration of ventilation was significantly reduced in HBCs group compared with NHBCs (WMD = 1.3 h; 95% CI, 1.9 to 0.6, \(P < 0.001\)). The ICU-LOS was significantly reduced in HBCs group (WMD, 9.3 h; 95% CI, 14.7 to 3.9, \(P < 0.001\)), and the same effect was observed in hospital LOS analysis (WMD, −0.5 day; 95% CI, −0.9 to −0.01, \(P = 0.02\)). Although there was a significant difference in favors of HBCs in the composite end-point (death, MI, stroke, re-sternotomy, wound infection and AF) (OR, 0.6; 95% CI, 0.5 to 0.8, \(P < 0.001\)), there were a marginal differences in favor of HBCs in the incidence of MI (OR, 0.6; 95% CI, 0.4—1, \(P = 0.06\)) and AF (OR, 0.7; 95% CI, 0.4—1.1, \(P = 0.08\)); (see Table 3). The use of low dose heparin in the HBCs group did not change the overall effect of HBCs in the relevant outcomes except in the incidence of AF, which become significantly less in the HBCs (\(P = 0.01\) compared with \(P = 0.08\) for the overall effect).

3.2. Subgroup and sensitivity analysis

Blood loss, PRC, platelets and FFP transfusion and ICU-LOS had high heterogeneity values as indicated by the \(I^2\) test,
50% (Table 3). Possible values of $I^2$ range from 0 to 100%, where 0% would indicate absence of heterogeneity and higher values indicate increasing degrees of heterogeneity. Post hoc sensitivity analysis was performed for each statistically significant outcome with high heterogeneity (Table 4). A sensitivity analysis of blood loss until removal of drains and ICU-LOS categories were carried out in the following subgroup: isolated CABG, elective procedure, high dose heparin, use of a Carmeda circuit, recent studies (1999 and onwards), high quality studies (Jadad scale 3), and double blinded studies. The heterogeneity was marginally reduced only in the ICU-LOS ($I^2 = 47.3%$), however the difference between the two groups became insignificant ($P = 0.55$). The significant difference that resulted in favors of the HBCs in this category, may have been due to observer bias, as the drains in the HBCs group may have been removed earlier compared with NHBCs group. This difference was completely

4. Discussion

This meta-analysis has shown that HBCs compared with NHBCs, reduces the number of patients who needed PRC transfusion by 20% (95% CI, 10—40%; number needed to treat (NNT) = 18) and re-sternotomy by 40% (95% CI, 20—60%; NNT = 32). It also reduced average duration of ventilation by 78 min (95% CI, 36—114), average ICU-LOS by 9.3 h (95% CI, 3.9—14.7) and average hospital LOS by 0.5 day (95% CI, 0.1—0.9). The present study evaluated the blood loss until the removal of drains category, because the majority of studies that reported blood loss used this endpoint (Table 3). The significant difference in favor of HBCs in minimizing blood loss postoperatively was no longer apparent in the double-blinded subgroup ($P = 0.75$).
eliminated in the double-blinded subgroup (one study). The number of patients in this study is small (Table 4), which might not be enough to show a statistically significant difference. However, if there was a real difference, it should have been seen in the blood loss evaluated at 24 h group as well. This was not the case.

Stammers et al. [138] demonstrated (in a review of RCTs) that HBCs have benefit over NHBCs in terms of total postoperative blood loss, ventilation time and ICU-LOS, but no significant difference in 24 h chest tube drainage. However, the exact definitions pertaining to postoperative blood loss was not clearly identified in this previously published work. Mahoney [139], suggested that covalently bonded circuits, like Carmeda have a clinical performance superior to that of ionically bonded circuits (e.g., Duraflo II), which are cheaper. This has been the subject of discussion in the published literature. It is important to mention that in Mahoney’s study non-randomized trials were included, which increases the likelihood of potential bias from that work and therefore reduce the strength of the inferences that can be drawn from this study. In the present study, the analysis of data in the Carmeda subgroup did not support Mahoney’s [139] previous conclusions.

The benefit of HBCs in reducing the duration of ventilation and ICU-LOS is consistent with the findings of Stammers et al. [138]. However, in his review the WMD for these two endpoints were larger than that in this present study. The duration of ventilation was (WMD, −5.9 h; 95% CI, −10.7 to −1.1) and the ICU-LOS was (WMD, −13.5 h; 95% CI, −22.8 to −4.1). Mahoney [139] reviewed 16 studies and showed that HBCs compared with NHBCs has significant effect in reducing postoperative blood loss, blood transfusion, duration of ventilation, ICU-LOS and hospital LOS. This study also showed cost benefit in using HBCs. However, these results were derived mainly from non-randomized trials. Therefore, caution must be exercised in interpreting these results because of the selection bias inherent in non-randomized trials.

5. Heterogeneity

This meta-analysis included many studies with different patient demographics, inclusion and exclusion criteria, surgical procedures and types of circuits. All of these may have contributed to clinical and methodological heterogeneity, which may subsequently, have resulted in statistical heterogeneity for some of the results. Heterogeneity is a common problem in systematic reviews and meta-analyses. If it arises, it should be investigated by attempting to explore the possible reasons underlying this heterogeneity. In high quality and double-blinded studies the heterogeneity should be minimal. However, in this review the heterogeneity did not disappear in high quality and double-blinded studies in Table 4. The persistence of heterogeneity may be explained by the difference in the characteristics and risk factors of patients recruited for each study.

In this meta-analysis excluded studies included pediatric trials, transplantation cases and auto-transfusion as the amount of blood loss is largely different from adult coronary artery bypass and valve surgery compared with these types of cases. The majority of included studies recruited non-emergency and low-risk patients (Table 1).

6. Study limitations

As the majority of the included trials excluded emergency, re-do and high-risk patients, the inferences of this meta-analysis cannot be applied to these subgroups. Also it was not
As expected, some reviews have shown that the type of cardiotomy suction does not bear an effect on the outcome. As for non-coated cardiotomy suction, as the majority of studies did not document which one have been used, however, previous non-coated cardiotomy suction, as many soft endpoints like time of drain removal, it becomes very difficult to eliminate bias which may have been left to the investigator’s own definition, and if this combined with the fact that only few studies were blinded, it becomes very difficult to eliminate bias which may have been contributed to the statistical heterogeneity noticed above. Although the average Jadad quality score was 2.7 of 5, this is common for meta-analysis of randomized trials and does not necessarily mean the trials were of low quality but rather simply that key methodological details were not well reported.

### Table 4

**Subgroup analysis**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Blood loss until removal of drains</th>
<th>ICU-LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F</td>
<td>R</td>
</tr>
<tr>
<td>Overall</td>
<td>-118.8</td>
<td>-164.2</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-129.9, 107.7)</td>
<td>(-262.1, -66.3)</td>
</tr>
<tr>
<td>n (N)</td>
<td>526 (13)</td>
<td>858 (12)</td>
</tr>
<tr>
<td>CABG</td>
<td>-117.9</td>
<td>-167.8</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-129.1, -106.7)</td>
<td>(-275.9, -59.7)</td>
</tr>
<tr>
<td>n (N)</td>
<td>518 (11)</td>
<td>816 (10)</td>
</tr>
<tr>
<td>Elective</td>
<td>-47.8</td>
<td>-188.4</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-68.9, -26.7)</td>
<td>(-312.9, -63.9)</td>
</tr>
<tr>
<td>n (N)</td>
<td>398 (8)</td>
<td>816 (10)</td>
</tr>
<tr>
<td>High dose heparin</td>
<td>-111</td>
<td>-159.5</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-122.5, -99.5)</td>
<td>(-265.9, -53.0)</td>
</tr>
<tr>
<td>n (N)</td>
<td>542 (12)</td>
<td>624 (11)</td>
</tr>
<tr>
<td>Carmeda circuit</td>
<td>-242.6</td>
<td>-334.3</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-281.1, -204.1)</td>
<td>(-468.8, -199.8)</td>
</tr>
<tr>
<td>n (N)</td>
<td>76 (4)</td>
<td>171 (3)</td>
</tr>
<tr>
<td>Recent studies</td>
<td>-231.2</td>
<td>-176.5</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-247.5, -214.9)</td>
<td>(-303.9, -48.9)</td>
</tr>
<tr>
<td>n (N)</td>
<td>164 (3)</td>
<td>516 (9)</td>
</tr>
<tr>
<td>High quality</td>
<td>-183.3</td>
<td>-150.6</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-260.5, -106.1)</td>
<td>(-310.9, -9.8)</td>
</tr>
<tr>
<td>n (N)</td>
<td>167 (3)</td>
<td>423 (6)</td>
</tr>
<tr>
<td>Double blinded</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(-161.6, 225.6)</td>
<td>(-161.6, 225.6)</td>
</tr>
<tr>
<td>n (N)</td>
<td>60 (1)</td>
<td>272 (4)</td>
</tr>
</tbody>
</table>

F: fixed effect model, R: random effect model, WMD: weighted mean difference, I²: heterogeneity test (significant if I² > 50%). P: overall effect, n: number of subject, N: number of studies. Recent study (<1998), high quality (Jadad score ≥ 3).
reported [142]. Most of included trials have a Jadad quality scores of 3 or less because of the lack of blinding. This is related to the fact that most of these trials have primary endpoints of inflammatory responses which were evaluated by laboratory tests, and because the laboratory technician was likely to be blinded for patient allocation in the trial. However, the strengths of this meta-analysis result from strict adherence to the QUOROM guidelines, detailed systematic search and well defined inclusion and exclusion criteria.

7. Implications for clinical decision-making and future research

The evaluation of new technology is a multi-dimensional process which needs appropriately designed RCTs to evaluate the effect on specific and well-defined end-points. Although this meta-analysis delineates the landscape of existing evidence, it also serves to highlight gaps that remain. Most notable is the lack of published research in high-risk patients, as clinically relevant endpoints such as death and stroke would be more prevalent in this group of patients. Future clinical trials are unlikely to find a clinically significant difference in mortality and stroke in low to medium risk patients similar to those included in this analysis. Further evaluation of the cost-benefit of using HBCs in routine cases is also needed, as it is clear from the present study that HBCs have a positive impact on reducing the re-sternotomy, duration of ventilation, ICU and hospital stay, all of which may have a potential of cost saving. HBCs decrease the incidence of PRC transfusion by 20% (95% CI, 10—40%) and re-sternotomy by 40% (95% CI, 20—60%). It also decreases the duration of ventilation by 78 min (95% CI, 36—114 min); ICU stay by 9.3 h (95% CI, 3.9—14.7 h); and hospital stay by 0.5 day (95% CI, 0.1—0.9 day). One pooled cost analysis study has evaluated costs relevant to clinical outcomes when using HBCs [139]. This showed a cost saving of $3231 for covalently bonded circuits and $1068 for non-covalently bonded circuits due to improved clinical outcomes such as reduced LOS and reduced transfusion need.

HBCs have the potential to improve resource utilization compared with traditional circuits in patients undergoing cardiac surgery. However changing routine clinical and surgical practice needs the dispersal of evidence so as to facilitate the utilization of potentially disruptive new technology.

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