Positive impacts of Patient Blood Management in total hip arthroplasty. Retrospective and prospective studies (N=700)

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INTRODUCTION

Prosthetic hip replacement is a potentially hemorrhagic surgery with significant risk of transfusion of allogeneic labile blood products. However, practices in terms of blood product prescription vary widely from one institution to another. Additionally, in each institution, practices vary from one unit to another, and in each unit, from one prescriber to another.

Policy recommendations are based on the nature and use of blood components, the approach performed during surgery, the patient’s clinical condition and his biological parameters (based mainly on hemoglobin levels). Nevertheless, surgical techniques and practitioners’ skills are in constant evolution. Therefore, review of these practices is necessary at regular intervals and, consequently, policy updates are indispensable since, to this day, transfusing a patient remains a nontrivial gesture. Indeed, even if over the past years the number of transfusion-transmitted infections (TTIs) has clearly decreased (4,13,17,19), the risks of immunological and bacterial infections as well as the risk of transfusional accidents due to handling errors are still present (3). Blood transfusion costs are also far from negligible (12).

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A contrario, the adverse effects of post-operative anemia such as lower postoperative functional scores, increased mortality, increased cardiovascular risks, and longer hospital stays have been well demonstrated (5,7,14,18).

Thus, the authors proposed a retrospective study of blood consumption data of patients who underwent prosthetic total hip replacement in their department. Subsequently, based on the observed results that highlighted the transfusional practices, the authors prospectively analyzed the impact of implementing a Patient Blood Management policy for elective hip replacement surgery.

MATERIALS AND METHODS

Patient selection for the retrospective study

All medical records between 2009 and 2011 regarding patients who had a total hip replacement in our orthopedic department were reviewed. Prostheses implanted for fracture of the femoral neck were excluded from the cohort. A total of 577 patients who had undergone surgery at two different hospital sites were included. These hip replacements were performed by a staff of seven surgeons and anesthesiologists. Surgical approach varied from one surgeon to another. Four different approaches were observed: posterior, Hardinge, Rottinger (minimally invasive anterior approach) and Nazarian (transgluteal) approaches. In this study, no investigation was made concerning the type of implant nor the kind of fixation used.

Other data concerning surgeons and approaches used for the procedure, information on the patient’s age, clinical status, pre- and postoperative hemoglobin levels, as well as number of units transfused, day of transfusion, type of transfusion were collected.

From 2009 to 2011, no coherent transfusion policy existed in the department. Practices in terms of prescription and blood compound transfusions were highly variable between prescribers. The only constant was the systematic order the day prior surgery of 3 or 4 concentrated leuko-depleted red blood cell units. These were ordered regardless of preoperative hemoglobin levels and the patient’s global medical condition.

Recommendations and transfusion strategy

Given the results of the retrospective study, a Patient Blood Management (PBM) policy was created and implemented in the authors’ department. PBM was based on 3 pillars: (i) Optimization of patient’s blood volume (notably in terms of red blood cell mass); (ii) Minimization of patient’s blood loss; (iii) Optimization of patient’s physiological tolerance to anemia.

Seven new recommendations were developed and then implemented in 2012 in our orthopedic surgery department:

1. Improve patient selection in terms of comorbidities.
2. Cancel programmed autologous transfusions.
3. Set transfusion threshold at 8 grams of hemoglobin per deciliter, exceptions made under particular medical circumstances.
4. Raise surgeons’ and anesthesiologists’ awareness of the importance of reducing intraoperative blood loss.
5. Limit post-operative blood tests to those strictly necessary.
6. Speed up delivery of blood bank allogeneic blood products used only when necessary - to minimize unnecessary preoperative orders.
7. Define a strategy for preoperative anemia.

Patient selection for the prospective study

In 2012, all surgeons and anesthesiologists of the orthopedic department were informed of the results of the retrospective study and the entire staff was asked to implement Patient Blood Management policy including the seven new recommendations in the specific context of total hip arthroplasty for an indication other than post traumatic. In addition, they were all informed that a prospective study would later evaluate the PBM’s effects.

The authors therefore carried out beginning 1 October 2013 to 31 March 2014, a prospective study that examined a cohort of 123 patients. The
prospective study involved the same surgery, by the same surgeons (N = 7) and the same anesthesiologists (N = 20) as in the retrospective study. Surgical techniques did not change between the entire study periods. The same parameters, as described previously, were analyzed. Note that during this time, the two hospital sites restructured permitting the procedures to take place in a single operating ward.

Only data concerning the use of intraoperative blood salvage procedure were added to the prospective study.

Statistical analysis

Statistics were analyzed using JMP Statistical Discovery Software (JMP France, Brie Comte Robert, France). Student and Turkey tests were used to compare patients’ ages at year of the study. Khi-carre from Pearson test was used to compare, between 2009 and 2013, total transfusion rates and more specifically transfusion timing in regards to the surgery (day 0 or day > 0), and transfusion volume, in units of allogeneic Labile Blood Products - LBP - (<4 or ≥ 4). Student test was used to compare the 7 surgeons and the 4 surgical approaches in terms of prevalence of anemia and blood loss (ΔHb). In all these tests, a p-value < 0.05 was considered statistically significant.

RESULTS

Retrospective study: groups A and B

Between January 2009 and December 2011, 577 patients underwent elective hip replacement in our department. Prostheses implanted for femoral neck fractures were excluded beforehand. Of these 577 patients, 26 were part of an autologous transfusion program ABP (Autologous Blood Procurement). These 26 ABP patients formed group A, the rest of the cohort, transfused with allogeneic LBP (Labile Blood Products), formed group B (N = 551).

Group A: patients with autologous blood product transfusions (N = 26)

The average age of patients in group A was 68 years old (range from 35 to 72 years) for an M/F sex ratio of 1 (Fig.1 and Table 1). These patients were transfused with their previously donated blood on the day of surgery (D0) or postoperatively (D>0), with an average of 2.4 units per patient. 18 of 26 patients (= 70%) received autologous transfusion although their hemoglobin level was greater than or equal to 9.5 gr / dl. Two of the 26 patients (= 15%) received additional allogeneic LBP. One of them received 1 red blood cell unit and the other, 2 fresh frozen plasma units.

Group B: patients with allogeneic blood product transfusions (N = 551)

In total, the group B included 551 patients who underwent a hip replacement between 2009 and 2011. The average age was 68 years old (range of 25-91 years), with no significant difference between 2009, 2010 and 2011 (p-value> 0.05) (Fig. 1 and Table 1).

As shown in Table 1, the proportion of women was predominant in 2009, 2010 and 2011. M/F sex ratios were respectively 0.63, 0.69 and 0.57. Throughout this retrospective study, we observed a preoperative prescription of LBP for 100% of patients. These prescribed packages were preoperatively set aside in the blood bank and then brought

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To the operating room on day 0. During the first three years, the allogeneic LBP transfusion rates were 28.3%. There was a significant decrease (p-value <0.05) from 2009 to 2011. Indeed, the percentage of transfused patients was respectively 34.6, 29.3 and 21.9% for 2009, 2010 and 2011. The transfusion rate at D0 and D>0 also showed a significant decrease (p-value <0.05) between 2009 and 2011. At D0, the transfusion rate was 12.8%, 9.1% and 4.3% respectively in 2009, 2010 and 2011 and at D>0, 21.8%, 20.2% and 17.6% respectively in 2009, 2010 and 2011. Furthermore, transfusion volume followed 2 different patterns. In one hand, low volume transfusions of <4 units/patient declined during 2009-2011. On the other hand, high volume transfusions of ≥ 4 units/patient remained stable, evaluated at 3.8% of total transfusion rates (p-value> 0.05).

Table II shows the existence from 2009 to 2011 of a significant disparity in the number of total hip arthroplasty per surgeon per year. We also observe that the mean preoperative hemoglobin levels (g/dL) and the percentage of preoperative anemic patients were not statistically different (p-value> 0.05). However, the diminution of hemoglobin levels after surgical procedure (∆Hb = {Hb observed preoperatively} − {lowest Hb level observed postoperatively}) and the percentages of transfused patients were significantly different for each surgeon (p-value <0.05). For example, we observed 25% transfused patients for the surgeon E against 12.4% for the surgeon F. Another example, the surgeon D transfuses from 1.8 to 4.4 times more patients than 6 other surgeons and seems to have a more hemorrhagic surgery with a median ∆Hb of 4.2 g/dL. Even if the definition of anemia was identical for all surgeons: an Hb <12 g/dL in women and Hb <13 g/dL in men (12).

Table III shows notable differences in median ∆Hb with the type of surgical approach. Three surgeons (A, C and F) used a posterior approach, two surgeons (B and E) practiced Hardinge approach, and one surgeon (D) used Nazarian approach. For his part, surgeon G practiced Rottinger (minimally invasive anterior approach) or Hardinge approaches. Median ∆Hb for posterior, Hardinge and Nazarian surgical approaches were respectively 3.5, 3.2 and 4.2 g/dL.

Prospective study: Group C

Between 1 October 2013 and 31 March 2014, 123 patients underwent elective total hip prosthesis surgery in our department and formed Group C. Prostheses implanted for femoral neck fracture were previously excluded. No patient from group
Table II. — Transfusion parameters according to the surgeon (A to G) in retrospective and prospective studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Parameters</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective</td>
<td>Number of patients (N=551)</td>
<td>101</td>
<td>121</td>
<td>40</td>
<td>80</td>
<td>40</td>
<td>113</td>
<td>54</td>
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<tr>
<td></td>
<td>Median pre-op Hb (g/dL)</td>
<td>13.7</td>
<td>13.9</td>
<td>13.2</td>
<td>13.3</td>
<td>13.3</td>
<td>14.3</td>
<td>13.7</td>
</tr>
<tr>
<td></td>
<td>% of preoperative anemic patients</td>
<td>13.9</td>
<td>14.1</td>
<td>22.5</td>
<td>15.0</td>
<td>25.0</td>
<td>12.4</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>% of transfused patients</td>
<td>16.8</td>
<td>18.2</td>
<td>35.0</td>
<td>65.0</td>
<td>22.5</td>
<td>30.1</td>
<td>14.8</td>
</tr>
<tr>
<td></td>
<td>Median Δ Hb (g/dL)</td>
<td>3.6</td>
<td>3.2</td>
<td>3.3</td>
<td>4.2</td>
<td>3.2</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>Prospective</td>
<td>Number of patients (N=123)</td>
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<td>21</td>
<td>7</td>
<td>4</td>
<td>33</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Median pre-op Hb (g/dL)</td>
<td>13.9</td>
<td>14.7</td>
<td>14.2</td>
<td>14.3</td>
<td>14.3</td>
<td>14.5</td>
<td>14.2</td>
</tr>
<tr>
<td></td>
<td>% of preoperative anemic patients</td>
<td>18.8</td>
<td>11.8</td>
<td>4.8</td>
<td>0</td>
<td>0</td>
<td>11.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of transfused patients</td>
<td>12.5</td>
<td>0</td>
<td>4.8</td>
<td>0</td>
<td>0</td>
<td>3.0</td>
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</tr>
<tr>
<td></td>
<td>Median Δ Hb (g/dL)</td>
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<td>3.0</td>
<td>3.1</td>
<td>4.5</td>
<td>3.3</td>
<td>3.7</td>
<td>3.2</td>
</tr>
</tbody>
</table>

Table III. — Transfusion parameters according to surgical approach: Posterior, Hardinge, Nazarian and Rottinger or Hardinge in retrospective and prospective studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Parameter</th>
<th>Posterior approach</th>
<th>Hardinge approach</th>
<th>Nazarian approach</th>
<th>Rottinger or Hardinge approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective</td>
<td>Number of patients (N=551)</td>
<td>254</td>
<td>161</td>
<td>80</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>median pre-op Hb (g/dL)</td>
<td>13.7</td>
<td>13.8</td>
<td>13.3</td>
<td>13.7</td>
</tr>
<tr>
<td></td>
<td>% of pre-op anemic patients</td>
<td>14.6</td>
<td>16.8</td>
<td>15.0</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>% of transfused patients</td>
<td>25.6</td>
<td>19.2</td>
<td>65.0</td>
<td>14.8</td>
</tr>
<tr>
<td></td>
<td>median ΔHb (g/dL)</td>
<td>3.5</td>
<td>3.2</td>
<td>4.2</td>
<td>3.2</td>
</tr>
<tr>
<td>Prospective</td>
<td>Number of patients (N=123)</td>
<td>86</td>
<td>21</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>median pre-op Hb (g/dL)</td>
<td>14.2</td>
<td>14.6</td>
<td>14.3</td>
<td>14.2</td>
</tr>
<tr>
<td></td>
<td>% of pre-op anemic patients</td>
<td>8.1</td>
<td>9.5</td>
<td>0</td>
<td>11.1</td>
</tr>
<tr>
<td></td>
<td>% of transfused patients</td>
<td>7.0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>median ΔHb (g/dL)</td>
<td>3.2</td>
<td>3.1</td>
<td>4.5</td>
<td>3.2</td>
</tr>
</tbody>
</table>

C entered an autologous transfusion program and patients did not receive a preventive prescription of allogeneic Labile Blood Products (LBP).

The average age of Groupe C was 65 years (range from 26 to 88 years) for a M/F sex ratio of 0.98 (Fig. 1 and Table I). In 2013, the percentage of transfused patients was 4.8%, of which 0.8% at D0 and 0.8% of high volume transfusions (≥ 4 units/patient) in Group C. Just as in Group B, Group C showed significant disparities between different surgeons (as shown in Table II) in terms of number of prostheses implanted, percentage of transfused patients (0 to 12.5%), and loss of blood mass (median ΔHb from 2.8 to 4.5 g/dL). Unlike 2009-2011, we observed in 2013 a significant variation in patient preoperative anemia with rates ranging from 0 to 18.8%. Table III also shows significant variations in transfusion rates depending on the surgical approach.
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In the prospective study, intraoperative blood salvage procedure data was collected. In Group C, 12 patients benefited from the use of an intraoperative blood salvage procedure during surgery with an average of 176 ml of collected liquid. Of these 12 patients, only one male, was anemic preoperatively. However, this procedure was only used in one of 10 preoperatively anemic patients.

Finally, as we see in Figure 2, the implementation of Patient Blood Management policy in our unit in 2012 had several positive impacts on patients care. We have a statistically significant decrease of preoperative prescription of allogeneic labile blood product (p-values <0.0001). Additionally, the total number of transfused patients decreased consequentially, both in regards to the timing of the transfusion (D0 or at D>0) and the transfusion volume (<4 units or ≥ 4 units).

**DISCUSSION**

Patient blood management (PBM) is a multidisciplinary evidence-based policy created to optimize patient transfusion care. PBM policy evaluates every aspect of a patient’s condition, from managing their clinical status by making pertinent and thoughtful choices for transfusion, to reducing waste and salvaging allogeneic labile blood products. The aim is to stabilize their clinical condition and their red blood cell parameters (1).

In order to implement a PBM during total hip replacement’s surgery (for reasons other than post-traumatic), we initially analyzed the transfusion practices of each of the seven surgeons in our orthopedic department by establishing a retrospective study.

Between 2009 and 2011, the autotransfusion - also called autologous transfusion -, was used in 4.5% of the patients (N = 26/577). The autotransfusion for a scheduled surgery was preoperatively decided by the surgeon or the anesthesiologist. In accordance with Cushners et al (8) and Goldman et al (10), our retrospective study confirmed that the risk of inducing preoperative anemia and consequently increasing the need for intra- or postoperative transfusions, is directly linked to preoperative Autologous Blood Procurement (ABP).

In fact, ABP increases the overall risk of transfusions (autologous and homologous combined) as explained in Forgie et al (9)’s meta-analysis. Indeed, of the 26 patients who beneficed from an ABP, all of them were transfused and 15% additionally received allogeneic LBP (labile blood products). We also note that these autologous blood products were used even if the patient’s clinical condition did not warrant it.

With autologous transfusions, the patients are also exposed to the risks of bacterial infections as well as accidents due to handling errors. The costs of pre-donation programs are considerable since it adds complexity to blood bank management. These costs rise considerably if we administer EPO to the patient for blood enhancement before surgery (6,15).

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types, multiple irregular antibodies or antibodies secondarily developed against a plasma protein (16).

The analysis of 2009-2011 data showed that the majority (71.7%) of preoperatively ordered LBP had not been used. Table I notably demonstrates low transfusion rates on day of surgery - D0 - (4.3%). From this evidence, we concluded that the preventive blood prescriptions were useless. Preoperative prescriptions are generally based on recommendations or transfusion practices that should be reconsidered constantly. In 2012, in order to prevent unnecessary systematic preoperative prescriptions, we obtained an agreement with the blood bank for quick delivery of allogeneic LBP.

During the same period, while no PBM policy was in place, we observed a significant regression of allogeneic LBP transfusion rates between 2009 and 2011. Indeed, 34.6, 29.3 and 21.9% of patients were respectively transfused in 2009, 2010 and 2011 (Table I). This observation follows the trend reported in Belgium at the same period (3). The reasons for the consumption decrease in our country were varied and numerous: including changes of surgical techniques, new transfusion policies.

We also noticed that a surgeon (D) from our department, showed much greater transfusion rates than others - 65% - (Table II). His transfusion’s threshold was settled at 10 g/dL. The hemoglobin threshold for transfusion is currently the subject of great debate. The French Agency for Safety of Health Products (AFSSAPS) proposed in 2002, standardized thresholds: 7 g/dL for patients with no history of cardiovascular disease (CVD), 8-9 g/dL for patients with history of CVD and 10 g/dL for patients not tolerating lower hemoglobin concentrations (syncope, dyspnea, tachycardia, angina pectoris, orthostatic hypotension, transient ischemic attack) (2). Other suggested the use of a 7g/dL threshold for all patients, including cases of septic shock and severe sepsis (11). Table II shows that surgeon D seemed to have more hemorrhagic procedures than other surgeons since his ΔHb are the highest. Data is insufficient to establish if the blood loss is linked to his surgical approach.

In 2012, based on the interpretation of the data, a PBM policy was defined in order to reduce the number of transfusions, increase blood salvage and decrease the rate of preoperative anemia. Seven new recommendations were therefore implemented with the PBM policy. The recommendations successfully reduced preoperative prescriptions of allogeneic blood components, and decreased the percentage of transfused patients, either at D0 or D>0, or for <4 or ≥ 4 units (Fig. 2). These decreases were statistically significant but with some reserve, given the limited number of transfused patients in Group C (4.8% or N = 5). These new recommendations had no impact on the ΔHb, which could be explained by unchanged surgical techniques in our department between 2009 and 2013. This means that our PBM policy was not able to influence intraoperative blood salvage procedures.

In 2013, surgeons could have used intraoperative blood salvage devices on 10 preoperatively anemic patients. Unfortunately, this device was used only once. In our study, the decision of intraoperative blood salvage procedures remained largely anesthesiologist-dependent. Furthermore, better and earlier detection of preoperative anemia and judicious use of EPO remained difficult to implement in our department. Indeed, our PBM didn’t have the expected impact on the preoperative anemic rate of the patients. The percentage of anemic patients rose to 18.8% (surgeon A).

In conclusion, the benefits of implementing a PBM policy are particularly effective if the new recommendations are correctly followed. In our orthopedic ward, PBM allowed better patient care and considerable savings on health care costs. In addition, transfusion policy implementation within the framework of total hip replacements has positively impacted management of our blood bank and increased patient safety during transfusion. Finally, the very significant lowering of LBP transfusion rates has ethical implications as fewer donors are necessary. Subsequently, we plan to regularly review our transfusion rules to maintain or even improve efficiency of the Patient Blood Management policy. In the future, the two main objectives for our department are to detect as well as treat preoperative anemia and to develop intraoperative blood salvage methods.
REFERENCES

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