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ORIGINAL

POSTOPERATIVE BLOOD SALVAGE AFTER KNEE ARTHROPLASTY: ARE THEY STILL USEFUL? A RETROSPECTIVE COHORT STUDY

RECUPERADORES DE SANGRE POSTOPERATORIOS TRAS LA ARTROPLASTIA DE RODILLA: ¿SIGUEN SIENDO ÚTILES? UN ESTUDIO DE COHORTES RETROSPECTIVO

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Keywords:
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Palabras clave:
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Transfusión de Sangre;
Artroplastia;
Rodilla;
Anemia;
Factores de Riesgo.

Abstract

Background and Goal of Study: Blood salvage (BS) is important to implement the second pillar of Patient Blood Management to avoid anaemia after total knee arthroplasty (TKA). Our primary outcome was to assess BS usefulness to decrease allogenic blood transfusion (ABT) rate in TKA.

Materials and Methods: a retrospective, observational cohort study was conducted on consecutive patients scheduled for TKA with BS or not. Demographic, comorbidity, surgical and anesthetic data, laboratory pre and postoperative results, volume of blood drained, and reinfused from BS and the requirement of ABT were recorded. Parametric and non-parametric tests were employed. $p < 0.05$ was accepted as significant.

Results: 260 patients were included (130 per cohort). The amount of postoperative bleeding was 713.1 $\pm$445.4 ml. 26.5% received ABT. BS reduced transfusion in 13,1% (p=0,024) with RR 1,65 (CI 1,085-2,52)]. Risk factors for postoperative bleeding were: male gender, atrial fibrillation, preoperative anti-platelet therapy and cementless primary TKA. Risk factors for ABT: ASA > II, preoperative hemoglobin < 13 g/dl, knee revision, anti-platelet therapy, longer surgery time. Patients transfused had lower hemoglobin values (p<0.001), and longer medium LOS (+2.5 days, p=0.026).

Conclusion: The use of BS in TKA showed benefits reducing allogenic blood transfusion and length of hospital stay. BS would remain an effective, safe and cheap alternative to tranexamic acid in patients with high risk of thromboembolism events operated of TKA.

Resumen

Introducción y Objetivo: El recuperador de sangre es un elemento importante del segundo pilar para la optimización de la anemia perioperatoria tras la artroplastia de rodilla (ATR). El objetivo principal de este estudio es determinar la eficacia de los recuperadores de sangre (RS) postoperatorios para reducir la tasa de transfusión de sangre alogénica (TSA) en el postoperatorio de la artroplastia de rodilla.

Material y Métodos: Se realizó un estudio retrospectivo de cohortes en pacientes intervenidos de ATR comparando el grupo en el que se utilizó RS y el grupo sin RS. Se recogieron y analizaron los datos demográficos, comorbilidad, información relevante de la cirugía y el procedimiento anestésico, resultados de laboratorio pre y postoperatorios, volumen de sangre recogido en el drenaje, volumen de sangre transfundido del RS y la necesidad de TSA. Se realizaron los test paramétricos y no paramétricos correspondientes. Se aceptó como nivel de significación estadística p<0,05.

Resultados: Se incluyeron 260 pacientes (130 por cohorte). La hemorragia postoperatoria fue de 713.1 $\pm$445.4 ml. El 26.5% recibió TSA. En la cohorte con RS la incidencia de TSA disminuyó un 13% (p=0,024) con RR 1,65 (CI 1,085-2,52). Se identificaron como factores de riesgo de hemorragia postoperatoria: género masculino, fibrilación auricular, terapia antiagregante y ATR no cementada. Los factores de riesgo de TSA identificados fueron: ASA > II, Hb preoperatoria <13 g/dl, recambio de rodilla, terapia antiagregante y tiempo quirúrgico prolongado. Los pacientes transfundidos presentaron cifras postoperatorias de Hb menores (p<0,001), y una estancia hospitalaria más prolongada (p=0,026).

Conclusión: El uso de los RS postoperatorios en la ATR es una medida eficaz para disminuir la TSA y la estancia hospitalaria. Los RS podrían ser una alternativa eficaz, segura y económica al uso de ácido tranexámico en aquellos pacientes con un riesgo elevado de eventos tromboembólicos intervenidos de ATR.

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INTRODUCTION

The incidence of arthritis and arthrosis is increasing at the same rate as the age and comorbidities of our population in high income countries. Consequently, the costs, risks and complications after total knee arthroplasty (TKA) are also on the rise (1).

Postoperative bleeding after TKA is one of the important outcomes to control, to avoid postoperative complications, especially in patients with comorbidity. Bleeding is greater during the first 6 postoperative hours and can reach up to 800 mL (2). Between 20 and 30% of patients undergoing major orthopedic surgery present moderate anemia, and an increased risk of requiring blood transfusion. For patients who undergo TKA, forty to fifty percent require allogenic blood transfusion (ABT) in the perioperative period (3). Transfusion complications have been widely recognized by many international organizations and commissions and include allergic reactions, transfusion-related acute lung injury (TRALI), ABO-incompatible transfusion and transfusion errors, infections, immunomodulation/suppression (4) and is associated with an increased risk of short and long term mortality (5).

In Europe, ETPOS (European Transfusion Practice and Outcome Study) group observed that restrictive transfusion protocols were used only in 63% of hospitals and blood salvage (BS) are used in 6% (6). BS is an important system to implement the second pillar of Patient Blood Management approach. Its advantages are its few adverse effects (2,7) pro-inflammatory effect minimizing the immunosuppression due to trauma and hemorrhage (8) and decreasing of the rate of ABT (9,10).

The use of BS has dropped markedly during the last years, due to the implantation of other techniques of perioperative patient blood management. The aim of this study was to assess the interest of BS for the improvement of the postoperative results of ABT and postoperative anaemia in a population of patients scheduled for a total knee arthroplasty.

MATERIALS AND METHODS

After having obtained the approval of our local Ethics Committee, a retrospective, observational cohort study was conduced in consecutive patients scheduled for TKA throughout twelve months in a tertiary university hospital. The medical data of all consecutive patients scheduled for TKA during that period were systematically reviewed. Inclusion criteria were to have undergone primary or replacement knee arthroplasty, excluding those in whom tranexamic acid (TXA) was administered by any routes available, and those for whom data collected was incomplete. The study was carried out on patients scheduled for TKA who were exposed to BS or not.

Demographic, comorbidity, surgical and anesthetic data were recorded until hospital discharge. Hematology and coagulation pre and postoperative results were collected at 6, 24, 48 hours and at hospital discharge from hospital. The volume of blood drained and reinfused from BS as well as the requirement of ABT were also recorded.

Primary outcome was to assess whether the use of BS postoperative reduced ABT, influenced hemoglobin and hematocrit levels and length of hospital stay (LOS). Secondary outcomes were to define risk factors for bleeding and receiving ABT after knee arthroplasty and to assess the influence of ABT on LOS.

After carrying out a preliminary study, the total incidence of ABT after knee arthroplasty was estimated to 23.3%. The sample size was calculated to 260 patients (130 per cohort), for a statistical power of 0.8 and an α error of 0.05 aiming at reducing ABT incidence by 50% and achieving an ABT incidence inferior or equal to 11.65% with the use of BS.

Statistical analysis was performed using SPSS version 11 /version 21 (SPSS Inc. Chicago. Illinois. USA®). Parametric and non-parametric tests were employed. Homogeneity of the two groups for pre-BS variables were checked. Comparisons between patients having or not received BS were carried out with One-Way and Two-Way Anova and Chi-Square tests. $p< 0.05$ was accepted as significant.

RESULTS

260 were included in the study, in 130 BS was used and in 130 BS was not used (figure 1, flow diagram). Homogeneity was checked for both groups for pre-BS variables (Table 1). The most frequent indication for surgery was osteoarthritis in 90.7% of cases. Primary TKA was performed in 91.5% (88.5% cemented, 1.5% cementless, 1.5% computer assisted TKA) and revision in 8.5%. Age was 71.69 $\pm$8.6 years. 67,9% of patients was ASA II classification and 29,3% was ASA III. Hypertension was the most common comorbidity (70,4%). 18,5% received preoperative anti-platelet therapy (APT) (Table 2).

Lower limb ischemia was used in 96,1% of cases, and in 84,3% was released before closing. Ischemia time was 82.62$\pm$22.7 min. Duration of surgery was 103,1+24,2 min. Loco-regional anesthesia was predominant used in 96.9% of cases, of which 79.5% were spinal anesthesia. Femoral block was the most frequent analgesic technique. General anesthesia was performed only in 3.1% of the cases. 93,5% of patients presented postoperative bleeding, mean bleeding volume was 713,1 +445,4 ml. In 90% of cases, recuperated blood was transfused, and the re-infused volume from BS was 619.96 $\pm$352.7 mL.

TABLE 1.- Homogeneity results.

Cuantitative variables	BS	No BS	p	Cualitative variables	BS	No BS	p
Age	71,8	71,5	0,718	Gender Male /Female	30/100	34/96	0,666
Weight	77,52	78,89	0,427	ASA Classification: ASA I ASA II ASA III	5 91 30	2 78 43	0,102
Height	160,63	161,14	0,686	Cardiovascular diseases:			0,703
Analytic results:				Arterial hypertension	85	80	0,607
- Haemoglobin	13,82	13,63	0,245	Ischemic heart disease	16	11	0,417
- Haematocrit	41,75	41,69	0,891	Hematological diseases: Anemia Pulmonary embolism/ deep vein thrombosis Trombopenia Hemophilia Myeloproliferative Syndromes/Lymphoma	1 6 2 0 3	0 2 1 1 0	0,388
- Platelets	$230x10^3$	$241x10^3$	0,141	Anti-platelet therapy	22	24	0,352
- Protrombin activity	106,9	106,89	0,992	Anticoagulation therapy	10	9	0,817
- Fibrinogen	419,22	426,57	0,505	Preoperative LWMH treatment	9	9	1
- International Normalized Ratio (INR)	0,97	0,97	0,681	Tipe of surgery: Primary TKA Cementless TKA Replacement	116 3 9	114 1 13	0,627
- Cephalin rate	0,94	0,94	0,786	Anesthetic technic Spinal Combined General	91 32 4	115 12 3	0,500
Surgery time	103,29	102,92	0,904	Ischemia release moment: Before After	112 12	102 18	0,195
Ischemia time	82,28	82,98	0,812				
Total surgery time	151,90	155	0,498				
Postoperative bleeding	796,8	727,88	0,203				

p: statistic signification. ANOVA.
BS: blood salvage; LWMH: low weigh molecular heparin; TKA: total knee arthroplasty.

TABLE 2.- Comorbidities of study population	
Comorbidity	n (%)
ASA Classification:	
- ASA I	7 (2,8%)
- ASA II	169 (67,9%)
- ASA III	73 (29,3%)
- ASA IV	0 (0%)
Hypertension	183 (70,4%)
Auricular fibrillation	24 (9,2%)
Valvulopathy	15 (5,8%)
Ischemic heart disease	13 (5%)
Deep vein thrombosis	5 (1,9%)
Pulmonary embolism	3 (1,2%)
Thrombopenia	3 (1,2%)
Hemophilia	1 (0,4%)
Preoperative simple anti-platelet therapy	46 (17,8%)
Preoperative double anti-platelet therapy	2 (0,8%)
Anticoagulation therapy	19 (7,3%)
LWMH	18 (6,9%)

ASA Classification: American Society of Anesthesiologists Classification; LWMH: low weight molecular heparin.

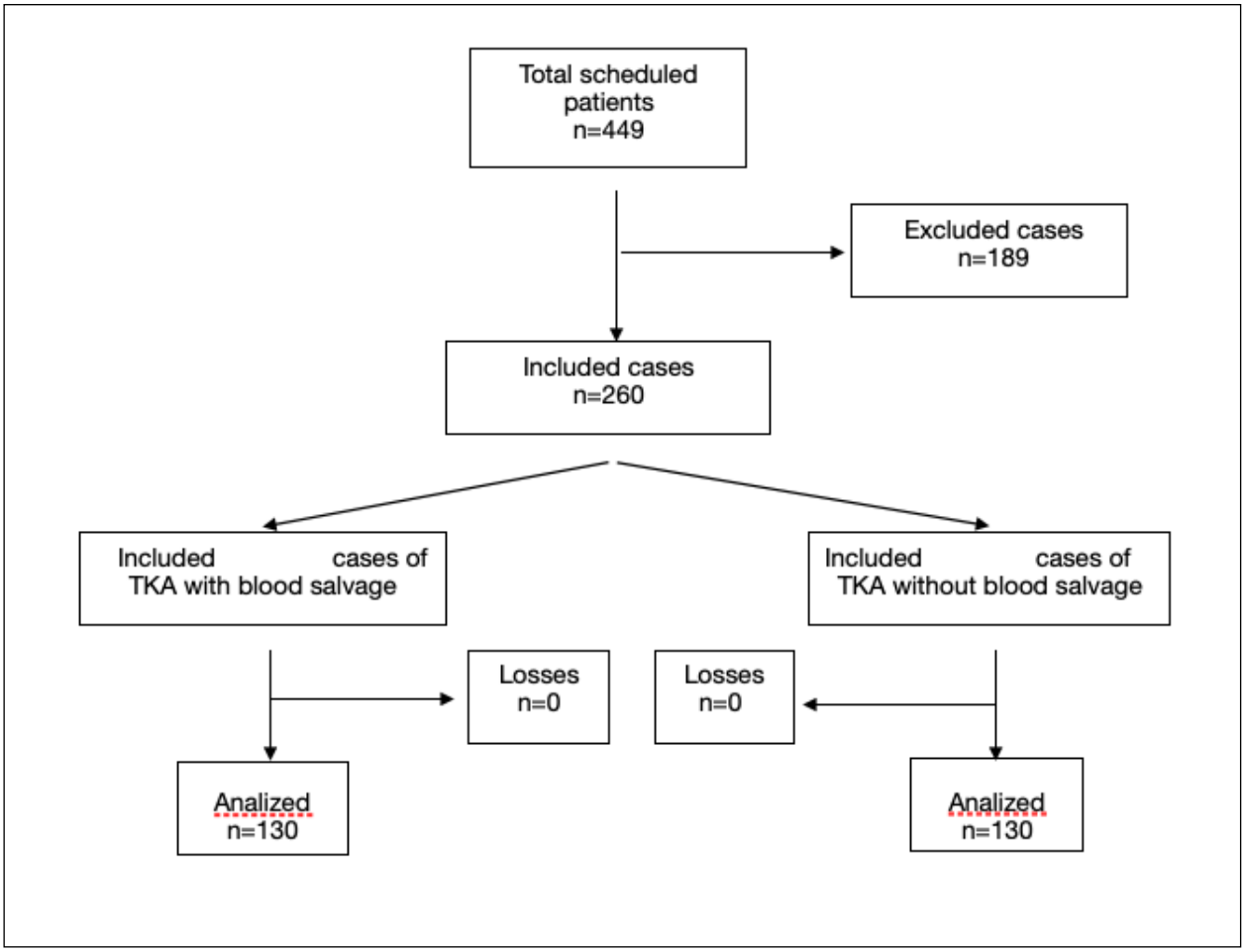

Figure 1. Consort diagram.

Dispite the existence of a Protocol for Preoperative Optimisation of Anaemia, this was not applied in all cases, resulting in 23.9% of patients who presented preoperative anaemia with hemoglobin levels (Hb) < 13 g/dL at the time of surgery. Only 2.4% had an Hb level < 11 g/dl being the lower Hb level 9.5 g/dl. Preoperative anaemia was significantly more prevalent in ASA (American Society of Anesthesiologists Classification) II and III patients (p=0,02). ABT prescription was guided by a Restrictive Transfusion Protocol (no patient receive packed red blood cells transfusion for Hb greater than 8 g/dL, or 10 mg/dL in cardiovascular risk patients, and that all of them were administered in one unit increments followed by re-evaluation of blood parameters). Patients who received ABT accounted for 26.5% of total cases, mainly in the late postoperative period (> 24 hours). 69.6% received 2 units of red blood cells and 11.6% received more than 2 units, equivalent to an average volume of 518.12±232.153 mL.

In the group without BS, 33.1% (43) patients received blood transfusion, versus 20% (26) in the group with BS exposed (OR: 95%CI 1.65 (CI 1.085-2.52); p=0.024). PACU time was 19.8 ± 15.8 hours and the length of hospital stay (LOS) was 9.8 ± 3.9 days (figure 2).

Patients in the BS exposed group had higher mean hemoglobin (Hb) (p= 0.029) and hematocrit (HTC) (p=0.009) at 24 and 48 hours than the non-BS group (figure 3). Furthermore, with a stratified analysis, patients treated with anti-platelet therapy (APT) without BS exposure received more ABT (58.3%) versus those without APT (25%), p=0.039. The use of BS had no influence on PACU time and overall hospitalization time. Male gender, atrial fibrillation, preoperative anti-platelet therapy and cementless primary TKA were identified as risk factors for postoperative bleeding (table 3). As expected, atrial fibrillation was associated with a significant increase in oral anticoagulation in 58.3% of patients and low weight molecular heparin (LWMH) therapy in 41.7% (p<0.001).

The ASA classification status ≥ II (figure 4), preoperative Hb values < 13 g/dl, knee revision, APT, longer surgery time and total time were identified as risk factors for ABT (table 3). Moreover, a higher preoperative Hb level was associated with a lower risk of transfusion (RR=1.959 [1.455-2.639]).

Anesthesia or postoperative analgesia technics did not influence the rate of ABT. Patients receiving ABT presented lower hemoglobin and hematocrit values (p<0.001), and a longer PACU time (+7 hours in PACU, p<0.001) and medium LOS (+2.5 days in LOS p=0.026).

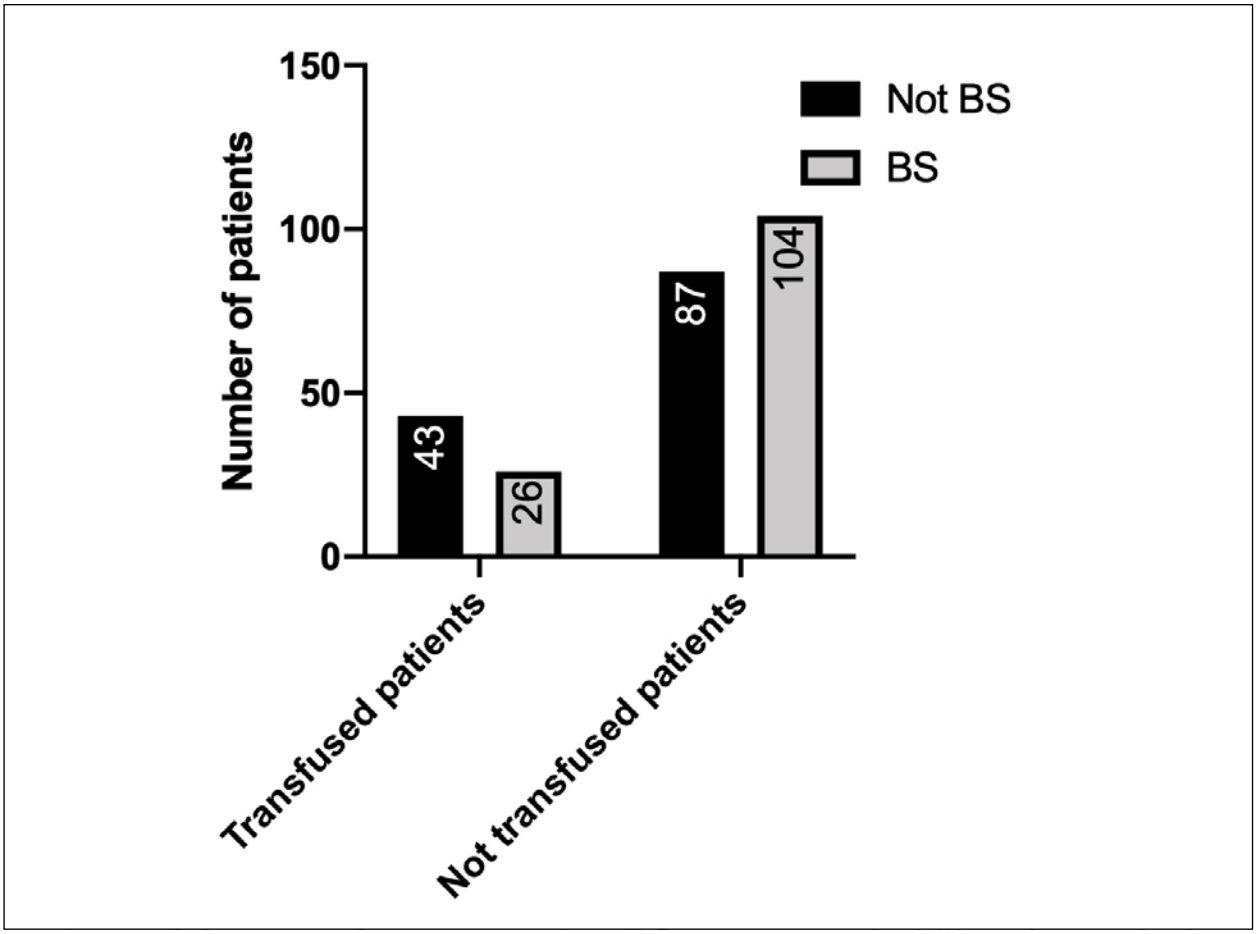

Figure 2. Comparison of the use of postoperative BS versus probability of transfusion. Results expressed as number and percentage [n (%)]. BS: Blood Salvage. Chi-square Test; p=0,024.

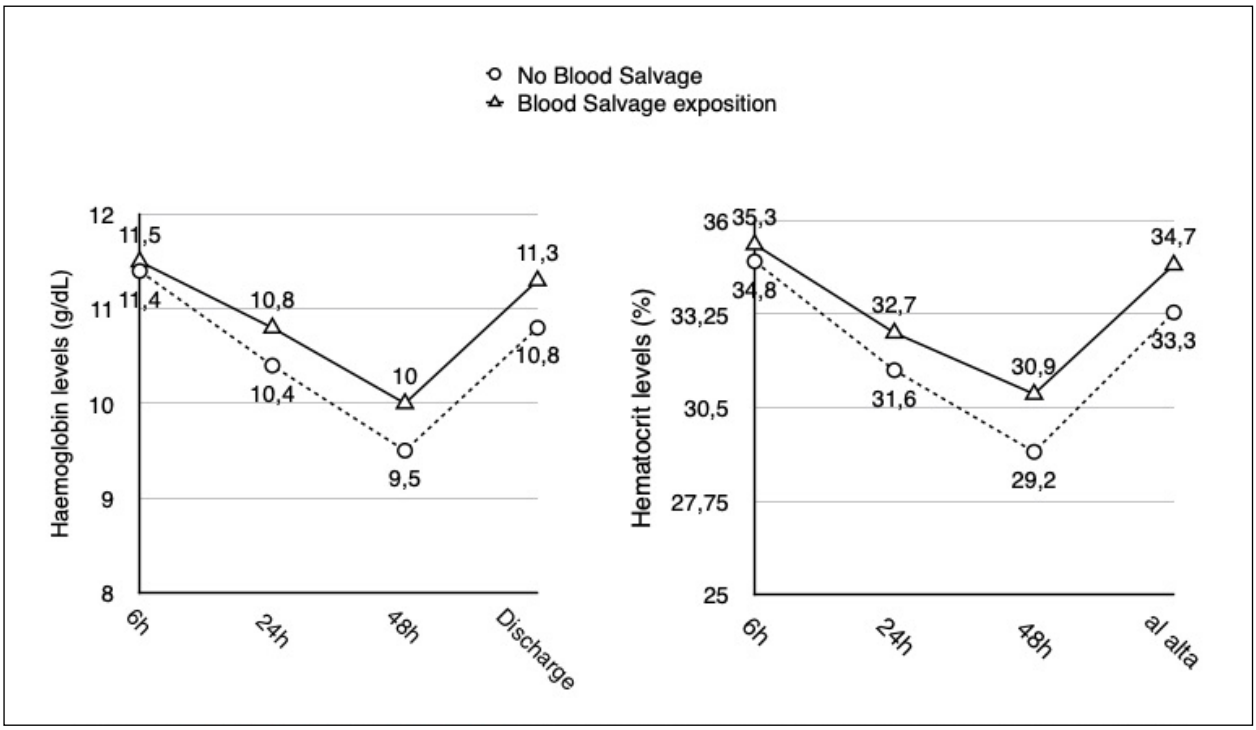

Figure 3. Haemoglobin and haematocrit levels during hospital stay in blood salvage exposed group and not exposed group.

TABLE 3.- Bleeding and allogenic blood transfusion risk factors		
Bleeding risk factor	mean ± SD (ml)	p
Male gender	Male 943,75 ± 528,08 Female 635,86 ± 385,84	< 0,001
Atrial Fibrillation	Yes 960,83 ± 647,84 No 687,4 ± 412,42	0,035
Anti-platelet therapy	Yes 847,45 ± 460,05 No 682,79 ± 437,51	0,022
Cementless Primary TKA	Cementless primary TKA 1200 ± 327,87 TKA revision 532,05 ± 325,86	0,017
Allogenic blood transfusion risk factors	n (%)	p
ASA clasification:		0,032
- ASA I	Yes ABT 0 (0%) No ABT 7 (100%)	
- ASA II	Yes ABT 41 (24,3%) No ABT 128 (75,7%)	
- ASA III	Yes ABT 27 (37%) No ABT 46 (63%)	
Preoperative Haemoglobin	ABT in Hb < 13 g/dl 35 (57,4%) ABT in Hb > 13 g/dl 32 (16,5%)	< 0,001
TKA revision	ABT in TKA revision 10 (45,5%) ABT in primary TKA 59 (24,8%)	0,045
Preoperative anti-platelet therapy	Yes ABT 20 (41,7%) No ABT 49 (23,1%)	0,011
Surgery time (minutes)	Yes ABT 110,07 ± 29,07 SD (min.) No ABT 100,62 ± 21,82 SD (min.)	0,006
Total time (minutes)	Yes ABT 162,7 + 31,44 SD (min.) No ABT 150,2 + 37,6 SD (min.)	0,016

TKA: total knee arthroplasty; ASA Classification: American Society of Anesthesiologists Classification; p: statistic signification.

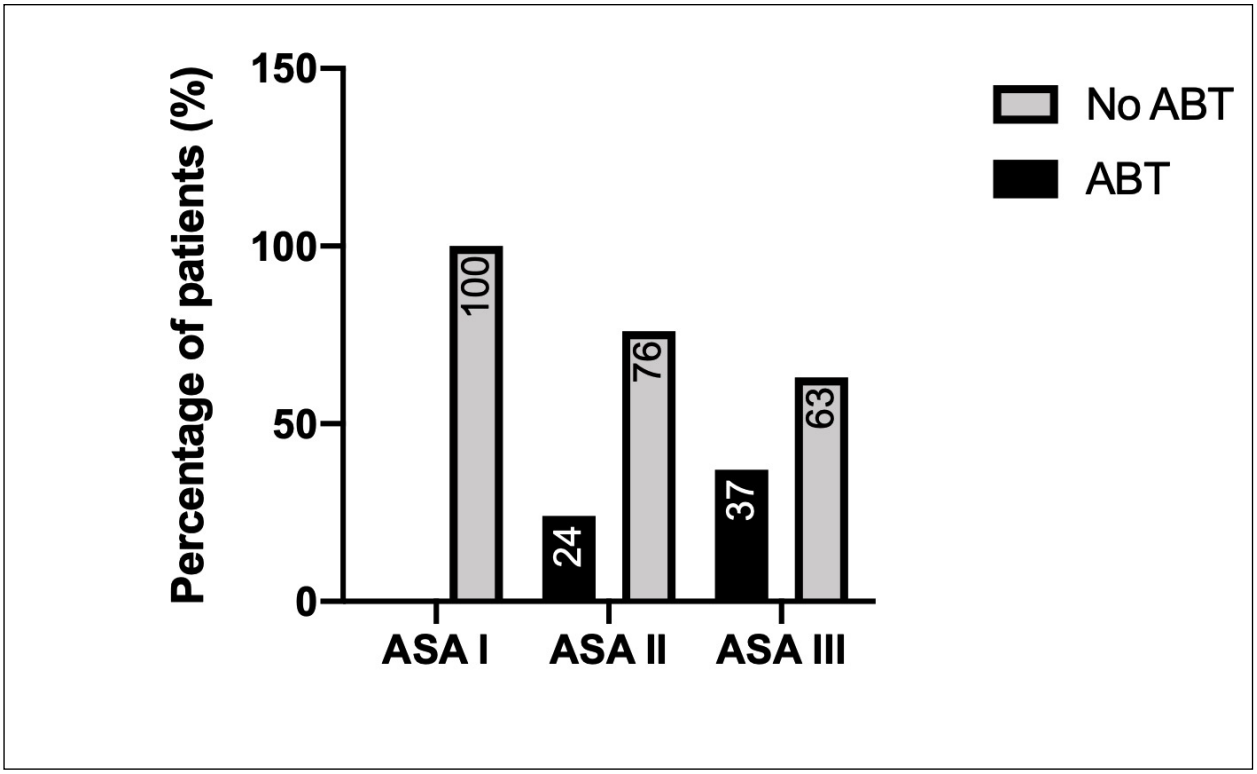

Figure 4. Transfusion rate depending on ASA Classification.
ABT: Allogenic blood transfusion; ASA: American Society of Anesthesiologists Classification.
Chi-square Test, p=0,032

DISCUSSION

In this retrospective observational study, we observed that BS strategies are an effective tool to achieve a significant reduction in ABT, and this is consistent with most published studies (table 4). *Muñoz et al. a*lso found a reduction in the number of blood units transfused (11). We couldn't confirm this reduction in our study because the sample size was not calculated for this variable. However, other authors like *So-Osman el al.* (12) did not either find any difference in transfusion rate, but their patients presented preoperative hemoglobin levels superior to 13 g/dl. No difference was found either by *Martin y von Strempel, Abuzakuk et al.* (13), *Tomasen et al.* (14) *and Cip et al.* (15) whose patients presented any rank of Hb. Nevertheless, *Tomasen's* study was performed in patients who were optimized preoperatively with a restrictive transfusion program. They received pre- and postoperative EPO treatment. This explains the very low transfusion rate (7.1%) hiding the positive effect of BS on ABT (15).

Patients with BS had higher Hemoglobin and Hematocrit values than those without BS during their whole hospital stay. They presented a decrease of Hb and Hematocrit at 48 hours and recovered on the fifth day. This trend is similar to the one described by *Zhou et al.*(16) *and Mayer-Rollnik*(17). *Kourtzis et al.* (12), *Sinclair et al.* (13), *Kirkos et al.* (18) *y Biarnés et al.* (19) also demonstrated the efficacy of BS in maintaining higher postoperative Hb and Htc values. *Moonen et al.* (10) and *Tomasen et al.* (15) described higher albeit non significative differences in the postoperative Hb values in the BS group. Our population's clinical and demographic characteristics were similar to other studies about TKA and total knee replacement (10,12,13,19,20,21).

The transfusion rate in our study was lower than that of other series. *Gombotz et al.* showed (22) is a wide variability between 20 and 50% (23.9% presented preoperative anaemia, Hb < 13 g/dl) was similar to those of *Saleh E. et al.* (4) (19.96%), *Hare et al.* (23) (20%) and those estimated by WHO for the world (25%) and Europe (28.7%) (24,25). However, patients in the study of *Saleh E. et al.* (26) presented more severe anaemia than those in our study. This high prevalence of preoperative anaemia might be due to a higher incidence of rheumatoid arthritis in their cohort of patients. This inflammatory disease is often accompanied by anaemia and the risk of ABT is increased three-fold (27,28).

The progressively aging population increases the need for arthroplasty. Associated comorbidity, mainly cardiovascular pathology, increases the need for anti-platelet and anticoagulant therapy. Very few studies address the issue of the influence of APT and anticoagulant therapy on orthopaedic surgery bleeding. We identified APT and LMWHT as the most important risk factors for bleeding and ABT as in *Burger et al.* (29) studied this outcome in a meta-analysis, as well as did the authors of the POISE-2 clinical trial (Perioperative Ischemia

Evaluation) (30,31). The latter did not support keeping preoperative APT in non-cardiac surgeries (32). *Gombotz et al.* (22) found also in TKR, THR and coronary by-pass, an increase in ABT with simple and double APT (43.8% and 62.6% respectively) at a similar rate to our results. Only found two retrospective studies described an increase in bleeding and/or ABT with no association with preoperative APT (33,34). Our study confirm these results.

We could not identify anticoagulation as a ABT risk factor despite other studies having shown it to be so (35). Likewise, ASA Classification status ≥ 3 was identified as a risk factor for complications during TKA recovery like anaemia and ABT. Similarly, preoperative anaemia is one of the most important and most studied transfusion risk factors, patients with Hb < 11 g/dl being those who would benefit most from preoperative hemoglobin optimization and blood-saving techniques like postoperative blood salvage (9, 27).

Surgery time has been widely identified in the literature as another bleeding and ABT risk factor. Therefore, reducing surgery time as much as possible improves productivity and reduces bleeding and ABT (10, 36, 37, 38). Equally, it has also been shown that ABT increases LOS and PACU time significantly with much lower Hb during the stay (11, 22).

In view of these results, the use of postoperative BS in TKA remains a good technique to reduce the need for ABT, minimizing the associated morbidity and mortality on this kind of surgery. Changes of practice in the last years have permitted to enter in the era of tranexamic acid, which has demonstrated its effectiveness. Nevertheless, there is a lack of evidence about its safety and the incidence of severe adverse events in high risk patients. In most randomized clinical trials, patients with thromboembolic diseases were excluded (39, 40). *Fillingham et al.* published a meta-analysis in 2018 and didn't either encounter any data concerning the incidence of arterial thrombosis (39). So, the published results on safety of tranexamic acid cannot be applied to patients with high risk of deep vein thrombosis and pulmonary embolism. However, high risk patients with an ASA ≥ 3 classification status didn't present a higher risk of developing vein thromboembolism in TKA, according to Fillingham meta-analysis (39).

TABLE 4.- Allogenic blood transfusion decrease with the use of postoperative BS in current literature.

Author, year	ABT withuot BS vs. BS used	ABT decrease	p
Thomas et al., 2001 [20]	28% vs. 7%	21 %	< 0,001
Abuzakuk et al., 2007 [14]	23% vs. 25%	Incremento de un 2%	No significativo
Moneen et al., 2007 [10]	16% vs. 2%	14 %	0,04
Muñoz et al., 2008 [11]	30% vs. 9%	21 %	0,001
Sinclair KC et al., 2009 [41]	52% vs. 25%	27 %	0,007
Park et al., 2012 [40]	26,7% vs. 0%	26,7 %	< 0,05
Fraga et al., 2013 [21]	42,19% vs. 20,18%	22 %	0,0017
Muñoz et al., 2013 [11]	24,5% vs. 8,5%	16 %	< 0,001
Cip et al., 2013 [13]	33% vs. 33%	0 %	0,999
Thomassen et al., 2014 [15]	7,3 % vs. 6,3%	1 %	0,857
*So-Osman et al., 2014** [12]	8,3% vs. 7,7%	0,6 %	0,19
Leigheb et al., 2016 [2]	34% vs. 10%	24 %	< 0,001
Valbuena	33,1% vs. 20%	13,1 %	0,024

* This study only included patients with > 13 g/dl Hb levels.

p: statistic signification; ABT: allogenic blood transfusion; BS: blood salvage.

CONCLUSIONS

In view of this results, we will be able to detect preoperatively those patients with a higher risk of hemorrhage and/or bleeding. This will allow us to improve their postoperative care after TKA. In the same way, all efforts must be focused on offering those patients with preoperative anaemia an effective optimization, which is one of the most important pillar of Patient Blood Management.

The use of blood salvage in TKA showed benefits reducing allogenic blood transfusion and length of hospital stay. Postoperative blood salvage would remain an effective, safe and cheap alternative to tranexamic acid, especially in those patients with a high risk of thromboembolism events operated of TKA, in which the use of tranexamic acid remains controversial.

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CONFLICT OF INTEREST STATEMENT

The authors of this article declare that they have no conflict of interest with respect to what is expressed in this work.

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