



Clinical Research

Impact of Hemoglobin Drop, Bleeding Events, and Red Blood Cell Transfusions on Long-term Mortality in Patients Undergoing Transaortic Valve Implantation

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ABSTRACT

Background: Despite the minimally invasive nature of transcatheter aortic valve implantation (TAVI), the procedure is associated with several complications. We aimed to analyze the individual impact of bleeding events, hemoglobin (Hb) drop, and red blood cell (RBC) transfusions on prognosis and to evaluate the temporal trends in bleeding and RBC transfusions since the initiation of the TAVI program in our centre and onward.

Methods: Consecutive patients (n = 597) undergoing transfemoral TAVI were prospectively enrolled. Periprocedural Hb levels, RBC transfusions, and major/life-threatening bleeding events were documented and analyzed.

Bleeding events leading to red blood cell (RBC) transfusion is a common complication in elderly and fragile patients undergoing transcatheter aortic valve implantation (TAVI), who often present with anemia on admission and frequently experience a further drop in hemoglobin (Hb) levels during hospitalization.¹ The clinical decision regarding the necessity for RBC transfusions in patients undergoing TAVI is challenging. In daily practice, RBC transfusions are often given to patients in the absence of overt major bleeding or hemodynamic instability.^{2,3} Furthermore, not all major bleeding events lead to a significant drop in Hb levels that necessarily require RBC transfusions. The clinical dilemma regarding the true benefit of RBC transfusion is further complicated by the fact that not only have periprocedural anemia and major bleeding been associated with reduced survival after TAVI but also that RBC transfusion per se has been reported to be associated with increased mortality.^{1,4-8}

RÉSUMÉ

Introduction : En dépit de sa nature minimalement invasive, l'implantation valvulaire aortique par cathéter (IVAC) est associée à de nombreuses complications. Nous avons pour objectif d'analyser les conséquences individuelles des événements hémorragiques, de la diminution de l'hémoglobine (Hb) et des transfusions de globules rouges (GR) sur le pronostic et d'évaluer les tendances temporelles des hémorragies et des transfusions de GR depuis la mise en route du programme d'IVAC à notre centre.

Méthodes : Les patients consécutifs (n = 597) subissant l'IVAC transfémorale étaient inscrits de manière prospective. Les taux péri-interventionnels de l'Hb, les transfusions de GR, et les événements

The aim of the present study was to evaluate the individual impact of major bleeding, Hb drop, and RBC transfusion on long-term mortality. We focus on the relationship between these 3 parameters and outcome and discuss the everyday clinical dilemma regarding the true benefit or potential harmful effects of RBC transfusions in patients undergoing TAVI. We also evaluated the temporal trends in bleeding and RBC transfusions since the initiation of the TAVI program in our centre and onward to determine the impact of the operator's learning curve on the rate of bleeding complications and on the use of RBC transfusions.

Methods**Study population**

Between March 2009 and March 2015, 597 consecutive patients undergoing transfemoral TAVI were enrolled at the Interventional Cardiology Unit of the Tel-Aviv Medical Center in Tel-Aviv, Israel. Informed consent was obtained from each patient as approved by the institutional ethics committee of our institution. The diagnosis of aortic stenosis was based on clinical, echocardiographic, and hemodynamic criteria.⁹ Suitability and eligibility for TAVI were determined by our heart team.

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Results: In the entire cohort, mean Hb level decreased after TAVI (11.8 ± 1.4 to 9.5 ± 1.3 g/dL; $P < 0.001$). Major/life threatening bleeding occurred in 66 (10.1%) patients, and 179 (30%) patients received RBC transfusions. Major/life threatening bleeding was not independently associated with mortality when adjusted for Hb drop and RBC transfusion. Among patients with an Hb drop of < 3 g/dL, those who received RBC transfusions had a higher mortality (hazard ratio [HR], 1.9; confidence interval [CI], 95% CI, 1.2-2.9; $P = 0.004$). Among patients with an Hb drop of ≥ 3 g/dL, the Hb drop had no significant impact on survival (HR, 1.5; 95% CI, 0.7-2.9; $P = 0.2$); however, patients who received RBC transfusions had a significantly higher mortality (HR, 4.1; 95% CI, 2.2-7.7; $P < 0.001$). The use of RBC transfusions decreased gradually over the duration of the study.

Conclusions: An Hb drop is frequently observed after TAVI. RBC transfusions are strongly associated with increased long-term mortality in these patients, regardless of the degree of Hb drop or major bleeding.

TAVI procedure

Four types of aortic valve prostheses were used: the CoréValve aortic valve prosthesis (Medtronic, Minneapolis, MN), the Edwards SAPIEN XT and S3 (Edwards Lifesciences, Irvine, CA), and St. Jude's Portico prosthesis (St Jude Medical, St Paul, MN). Valve type and size were planned before the procedure according to preprocedural echocardiographic and angiographic parameters. For all procedures, a single senior interventional cardiologist was responsible for all aspects of the case, including the administration of RBC units during the procedure. All periprocedural complications, including bleeding and vascular complications, were recorded.

After the procedure, patients were transferred to the intensive care unit for further observation. Postprocedural antiplatelet therapy consisted of clopidogrel 75 mg for 6 months and aspirin 100 mg indefinitely. For patients receiving chronic anticoagulation therapy, treatment was resumed shortly after TAVI and included anticoagulation and clopidogrel 75 mg.

Definition of bleeding

Bleeding events were classified as minor, major, and life-threatening according to the Valve Academic Research Consortium classification.¹⁰ Life-threatening bleeding was defined as fatal bleeding or bleeding from an organ causing hypovolemic shock or severe hypotension requiring vasopressors or surgery or bleeding from an overt source with a decrease in Hb of 5 g/dL or RBC transfusion of 4 units. Major bleeding was classified as overt bleeding, either associated with a decrease in hemoglobin of 3 g/dL or requiring transfusion of 2 or 3 units of RBCs without meeting "life-threatening" criteria. Minor bleeding was any bleeding of clinical significance (eg, access-site hematoma) that does not qualify as life-threatening or major.

Laboratory measurements and blood transfusions

The following Hb levels were recorded: preprocedural Hb was considered as the baseline Hb and the lowest Hb level

hémorragiques majeurs et mettant en danger la vie étaient documentés et analysés.

Résultats : Dans la cohorte entière, le taux moyen d'Hb ont diminué après l'IVAC ($11,8 \pm 1,4$ à $9,5 \pm 1,3$ g/dl; $P < 0,001$). Soixante-six (10,1 %) patients subissaient des hémorragies majeures et mettant en danger la vie, et 179 (30 %) patients recevaient des transfusions de GR. Les hémorragies majeures et mettant en danger la vie n'étaient pas indépendamment associées à la mortalité après ajustement en fonction de la diminution de l'Hb et de la transfusion de GR. Parmi les patients ayant une diminution de l'Hb < 3 g/dl, ceux qui recevaient les transfusions sanguines avaient une mortalité plus élevée (rapport de risque [RR], 1,9; intervalle de confiance [IC] à 95 %, 1,2-2,9; $P = 0,004$). Parmi les patients ayant une diminution de l'Hb de ≥ 3 g/dl, cette baisse n'avait pas de conséquence significative sur la survie (RR, 1,5; IC à 95 %, 0,7-2,9; $P = 0,2$). Cependant, les patients qui recevaient les transfusions sanguines avaient une mortalité significativement plus élevée (RR, 4,1; IC à 95 %, 2,2-7,7; $P < 0,001$). L'utilisation des transfusions de GR diminuait graduellement au cours de l'étude. **Conclusions :** Une diminution de l'Hb est fréquemment observée après l'IVAC. Les transfusions de GR sont fortement associées à l'augmentation de la mortalité à long terme chez ces patients, quel que soit le degré de la diminution de l'Hb ou l'hémorragie majeure.

during hospitalization was the nadir Hb; the Hb level at discharge was also recorded. Hb change was defined as the baseline Hb minus the nadir Hb.

There was no predefined Hb threshold to initiate an RBC transfusion, and the decision to conduct a periprocedural RBC transfusion was made by the treating interventional cardiologist or the anesthesiologist on a case-by-case basis. The data on RBC transfusions were recorded according to the institution's blood bank instructions.

Follow-up and mortality

After hospital discharge, follow-up visits were set at 1 month, 6 months, and 1 year. Patients were contacted by telephone yearly thereafter. Mortality data collected from civil registries or the referring physician were updated routinely and were available for all patients.

Statistical analysis

All data were displayed as mean (\pm standard deviation) for continuous variables and as the number (percentage) of patients in each group for categorical variables. The student t test and χ^2 test were used to evaluate the statistical significance between continuous and categorical variables, respectively. Binary logistic regression was used to evaluate the association between baseline characteristics and bleeding or blood transfusions. Odds ratios were calculated with a confidence interval (CI) of 95%. To define the impact of bleeding, Hb drop, and blood transfusion on mortality in the TAVI population, a forward stepwise Cox regression analysis was performed. Age and sex were entered into the initial analysis, followed by all other baseline clinical characteristics and Hb variables (baseline hemoglobin, nadir Hb, and Hb change as a continuous variable) and major and life-threatening bleeding events and RBC transfusions.

To study the relative effect of RBC transfusions on outcome, we divided our study population into 4 groups

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