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Original article

International point prevalence study of Intensive Care Unit transfusion practices—Pilot study in the Netherlands

suppl. Informations

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ABSTRACT

Background. – Anaemia and coagulopathy are common issues in critically ill patients. Transfusion can be lifesaving, however, is associated with potential life threatening adverse events. As an international transfusion guideline for this specific patient population is lacking, we hypothesize that a high heterogeneity in transfusion practices exists. In this pilot-study we assessed transfusion practice in a university hospital in the Netherlands and tested the feasibility of this protocol for an international multi-centre study.

Methods. – A prospective single centre cohort study was conducted. For seven days all consecutive non-readmitted patients to the adult Intensive Care Unit (ICU) were included and followed for 28 days. Patients were prospectively followed until ICU discharge or up to day 28. Patient outcome data was collected at day 28. Workload for this study protocol was scored in hours and missing data.

Results. – In total, 48 patients were included, needed in total three hours patient to include and collect all data, with 1.6% missing data showing the feasibility of the data acquisition. Six (12.5%) patients received red blood cells (RBCs), three patients (6.3%) received platelet concentrates, and two (4.2%) patients received plasma units. In total eight (16.7%) patients were transfused with one or more blood products. Median pre- and post-transfusion haemoglobin (Hb) levels were 7.6 (6.7–7.7) g/dL and 8.1 (7.6–8.7) g/dL, respectively.

Conclusion. – In this pilot-study we proved the feasibility of our protocol and observed in this small population a restrictive transfusion practice for all blood products.

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1. Introduction

Critically ill patients often receive a blood products to correct coagulopathy and/or improve oxygen delivery to peripheral tissues [1–4]. Administration of blood products can be lifesaving, but may also come with severe adverse events, varying from allergic reactions, acute haemolytic transfusion reactions, transfusion transmitted infections to transfusion related acute lung injury [5]. Since multiple large randomized controlled trials (RCTs) in the Intensive Care Unit (ICU) proved the safety of a restrictive red blood cell (RBC) transfusion strategy [6–8], an overall reduction in the proportion of patients who received a RBC transfusion was observed [2,9]. However, the superiority of a liberal RBC transfusion strategy is still debatable for different subpopulations; particularly patients with acute coronary syndrome and elderly patients might benefit from a liberal transfusion strategy compared to a restrictive strategy [10,11]. For plasma and platelet transfusions, well powered randomized controlled trials are lacking [12], also the definitions for liberal and restrictive transfusion strategies are not yet well defined. This lack of definition and research gap may explain the heterogeneous transfusion practices described in multiple studies [3,4,13]. Current platelet transfusion practice is mainly based on studies conducted in haemato-oncological patients or in low quality studies in critically ill patients. Furthermore, the effectiveness of a large number of plasma transfusions is not proven, and might even be harmful [14,15]. For plasma transfusion multiple alternatives exist, including administration of vitamin K and prothrombin complex, depending on the cause of the coagulopathy. However, these alternatives cannot completely replace plasma transfusion in critically ill patients.

Multiple observational studies have investigated transfusion practice in critically ill patients using questionnaires or examining patient cohorts. Limitations of these studies include focussing on only one blood product [2–4] or being single country [4,13,16] or single centre studies [17]. Since the administration of different blood products might be correlated [18], there is a need for a large international multicentre observational study that examines the administration of different blood products and coagulations factors. Considering the challenging character of these kind of studies, a pilot study is necessary to optimize the study protocol before enrolling it worldwide. In this pilot study, we assessed current transfusion practice in a university centre in the Netherlands and also assessed the feasibility of this study protocol and the case record forms (CRF) in preparation for a worldwide study.

2. Methods

2.1. Study design

A prospective cohort pilot study was conducted to examine current transfusion practices in a 32 bed mixed medical-surgical ICU in a Dutch university hospital. The patient population consisted of mixed surgical and medical ICU patients, including cardiothoracic surgery and patients with traumatic brain injury and brain haemorrhages. The data were part of routine care and were extracted from the electronic patient files. During a period of seven consecutive days all consecutive non readmitted patients at the ICU older than 18 years were included. Patients were prospectively followed until discharge with a maximum of 28 days. At the 28th day, patient outcomes were scored, regardless whether they were discharged (Fig. 1).

The Medical Research Ethics Committee of the Academical Medical Center in Amsterdam judged that this study is not subject to the requirements of the Medical research involving human subjects act. To use patient data, a written informed consent was obtained from the patient or a legal representative, using a deferred informed consent procedure. When the patient or their legal representative did not give consent for study participation, the patient was excluded from the study and data was not used for analysis.

2.2. Data collection

Data was collected prospectively by a research student (Appendix 1 for CRF).

Baseline characteristics included information about the demographics, comorbidities, Acute Physiologic Assessment and Chronic Health Evaluation (APACHE) IV score, type and reason of admission. Clinical and laboratory data were collected daily to compare patients who received a transfusion to patients who did not receive a transfusion, including nadir haemoglobin (Hb), nadir platelet count, highest prothrombin time (PT) and highest activated partial thromboplastin time (aPTT). For each transfusion event a short transfusion CRF was completed. A transfusion event was defined as a transfusion of a blood derived product or the administration of a coagulation factor, ordered within one order in the electronic patient system. For each type of blood product or transfusion (RBCs, plasma, platelets, coagulation factors including prothrombin complex, fibrinogen and tranexamic acid and activation of massive transfusion protocol) a separate CRF was designed. The 28-day

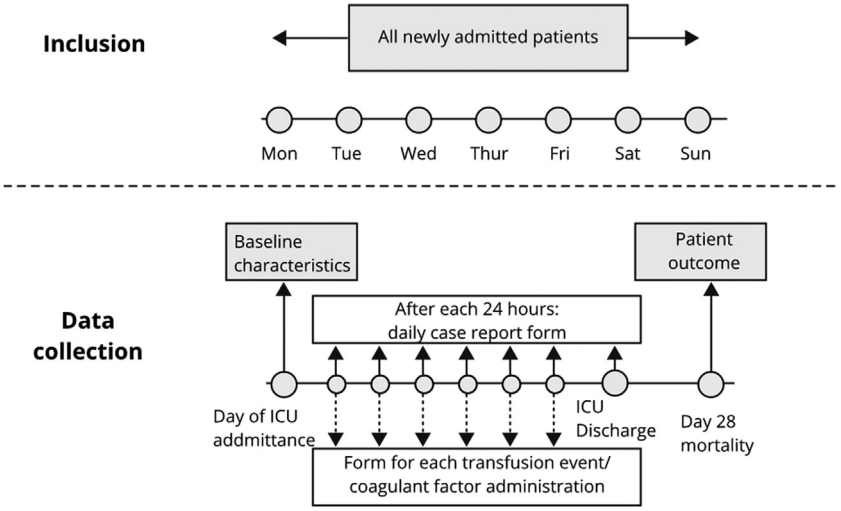

Fig. 1. Study design.

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mortality and the location of the patient (home, ward, ICU) were also collected.

2.3. Outcomes

The primary outcome of this study was to assess the current transfusion practice at our ICU, described by the number of RBC, platelet and plasma transfusions and the administration of coagulation factors, correlated with Hb levels, platelet count, INR/PT and fibrinogen prior to and post transfusion. The secondary outcome was the feasibility of the study protocol, assessed by the workload, missing data and the number of transfusion and administration of coagulation factors in this patient cohort. Furthermore, the design of a worldwide follow-up study was based on this pilot data.

2.4. Data analysis

The statistical analysis was performed using the statistical program R version 3.5.2. Continuous normally distributed data are presented in means (standard deviation) and not normally distributed data as medians (first-third quartile). The Wilcoxon sum rank test was used to test the dependence of two grouping variables on continuous, non-normally distributed data. Categorical variables were expressed as number and percentage. Categorical data were compared using the chi-square test. *P*-values below 0.05 were considered to be statistically significant.

3. Results

3.1. Patient characteristics

During the study week, 49 patients were found eligible for study participation. One patient did not consent and was withdrawn from study participation. Therefore, data from 48 patients were obtained and analysed. The majority of the patients was male 33 (67%) and the age of the study population was 68.5 (53–72) years. During the first 24 hours, 27 (56%) of the included patients received mechanical ventilation. Seventeen (35%) were admitted for treatment after cardiothoracic surgery, fifteen (31%) patients were admitted for non-surgical reasons. Other demographics, including reason of admission are shown in Table 1.

Table 1
Baseline characteristics.

Patient characteristics	
Age	68.5 (53.0–72.0) years
Gender men, *n* (%)	32 (67)
SOFA score	5 (3.0–7.0)
APACHE IV score	53 (40.0–71.5)
EuroSCORE	2.3 (1.0–3.4)
Type of admission, *n* (%)	
Elective	15 (31)
Urgent	2 (4)
Emergency	31 (65)
Referred from, *n* (%)	
Operating theatre	22 (46)
Other hospital	6 (12)
General ward	11 (23)
Emergency department	9 (19)
Reason of admission, *n* (%)	
Cardiovascular	18 (38)
Gastro-intestinal	5 (10)
Hematologic	1 (2)
Metabolic	2 (4)
Musculoskeletal/skin	3 (6)
Neurological	8 (17)
Respiratory	8 (17)
Sepsis	2 (4)
Other	1 (2)
Type of patient, *n* (%)	
Medical	15 (31)
Cardiothoracic surgery	17 (35)
Gastrointestinal surgery	6 (12)
Neurosurgery	5 (10)
Other surgery	5 (10)
Presence of shock, *n* (%)	
No	39 (81)
Anaphylactic	1 (2)
Cardiogenic	2 (4)
Hypovolemic	1 (2)
Neurogenic	1 (2)
Septic	4 (8)
Relevant comorbidities, *n* (%)	
ARDS	2 (4)
AKI	4 (8)
ACS	0
Other	21 (44)
Mechanical ventilation, *n* (%)	27 (56)
Supportive therapy, *n* (%)	
CVVH	1 (2)

Not normally distributed values are shown in median and interquartile range (IQR). Categorical variables are shown in number and percentage. SOFA: sequential organ failure; APACHE: Acute Physiologic Assessment and Chronic Health Evaluation; ARDS: acute respiratory syndrome; AKI: acute kidney injury; ACS: acute coronary syndrome; CVVH: continuous veno-venous hemofiltration.

3.2. Transfusion events

In total, 30 transfusion events and eight coagulation factor administrations were reported. Eight patients (17%) received one or more blood products and/or coagulation factors (Table 2). Forty patients (83%) did not receive any blood product or coagulation factor. The majority of the products were ordered by a resident (85%) and administered in the ICU (95%) (Table2). The remaining two products were transfused in the operating theatre; one platelet and one RBC concentrate.

3.3. Feasibility

The study related workload per included patient was on average three hours, including obtaining informed consent and data collection. The most time-consuming part of data collection was the baseline data, in particular calculating the APACHE IV score and EuroSCORE. Median time of collecting the baseline characteristics was 11 (9–14) minutes. The daily CRF was completed most often (167 times) with a median time of 4 (3–5) minutes per form.

Overall, the amount of missing data was limited (1.6%). In the demographics 0.8% of the data was missing, in all these cases the APACHE IV or EuroSCORE were missing. In the daily CRF, 1% of the data was missing: of this missing data the SOFA scores (40%), highest PT value (30%), and highest aPTT value (25%) were most frequently missing. The amount of missing data regarding transfusion events differed between the different blood products. Most frequently, data was missing in the coagulation factor form (11.9%), followed by plasma (3.1%), platelets (1.4%) and RBCs (1.0%) forms.

3.4. RBC transfusion

Median Hb levels were 10.9 (9.3–12.4) g/dL at ICU admission and 8.8 (7.9–9.1) g/dL in the remaining patients who were still admitted ($n = 6$) at day seven of ICU stay (Fig. 2A). During the study period, seventeen RBC transfusion events were registered. In total eight (12.5%) patients received one or more RBC transfusions. In eleven (65%) RBC transfusion events one RBC concentrate was transfused. In six (35%) events more than one unit was transfused. Non-single unit transfusion occurred only in bleeding patients. One patient received an irradiated RBC concentrate. RBC transfusion was mainly based on Hb triggers, in two cases other factors than Hb levels were considered (tachycardia and increased lactate levels).

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Table 2
Transfusion forms. Not normally distributed values are shown in median and interquartile range (IQR).

Transfusion events	
Product ordered by, *n* (%)	
Intensivist	2 (5)
Specialist, non-intensivist	2 (5)
Resident	34 (85)
Student	2 (5)
Location of transfusion, *n* (%)	
ICU	36 (95)
Operating theatre	2 (5)
Red blood cell transfusion	
Number of red blood cell transfusion events	17
Reason of transfusion, *n* (%)	
Low HB	12 (67)
Active bleeding	7 (39)
Hemodynamic instability	1 (6)
Other physiological triggers, *n* (%)	
None	16 (89)
Tachycardia	1 (6)
Lactate > 2 mmol/L	1 (6)
Hb level pre-transfusion, g/dL	7.6 (6.7–7.7)
Hb level threshold, g/dL	8.1 (6.9–8.1)
Hb level post-transfusion, g/dL	8.1 (7.6–8.7)
Increment after transfusion, g/dL	1.0 (0.5–1.1)
Number of transfused units	1.0 (1.0–2.0)
Platelet transfusion	
Number of platelet transfusions	11
Reason of transfusion, *n* (%)	
Active bleeding	4 (36)
Biopsy/BAL	3 (27)
Prophylactic without upcoming procedure	4 (36)
Antiplatelet use trigger for transfusion	2 (18)
Platelet count prior	10.0 (10.0–28.5) $\times 10^9$/L
Platelet count target	10.0 (10.0–50.0) $\times 10^9$/L
Platelet count post	13.0 (10.0–40.0) $\times 10^9$/L
Increment after transfusion	3.0 (0.0–15.5) $\times 10^9$/L
Number of transfused units	1.0 (1.0–1.5)
Plasma transfusion	
Number of plasma transfusion events	2
Reason of transfusion, *n* (%)	
Active bleeding	2 (100)
Pt prior, s	12.6 (12.1–13.2)
Pt post, s	12.6 (12.2–12.9)
Anticoagulant use trigger for transfusion, *n* (%)	1 (50)
Coagulation factors administration	
Number of coagulation factor events	8
Drug administrated, *n* (%)	
Tranexamic acid	5 (63)
Fibrinogen	2 (25)
Prothrombin	1 (13)
Reason of administration, *n* (%)	
Active bleeding	5 (63)
Biopsy	2 (25)
Prophylactic without upcoming procedure	0 (0)
Study	1 (13)
Massive transfusion protocol	0

Categorical variables are shown in number and percentage. ICU: Intensive Care Unit; HB: haemoglobin; BAL: bronchoalveolar lavage; Pt: prothrombin time.

Table 3
Patient outcome.

Day 28	
Patients state: died	
Died at ICU (%)	6 (13)
Died at another location than ICU	0
Days admitted on ICU	2.0 (2.0–4.3)
Location of alive patients, *n* (%)	
ICU	2 (5)
General ward	5 (12)
Discharged	35 (83)

Not normally distributed values are shown in median and interquartile range (IQR). Categorical variables are shown in number and percentage. ICU: Intensive Care Unit.

Pre transfusion Hb levels in bleeding and non-bleeding patients were 7.7 (7.3–8.1) and 6.8 (6.5–7.7) g/dL, respectively, however, this difference was not statistically significant ($P = 0.15$). Haemoglobin increment after a RBC transfusion event was 1.0 (0.5–1.1) g/dL (Fig. 3A), also this was similar in bleeding and non-bleeding patients ($P = 0.88$).

3.5. Platelet transfusion

During the first week of admittance, the mean nadir platelet count remained stable: the median nadir platelet count was 160×10^9 cells/L (122–276) and 163×10^9 cells/L (100–287) at day one ($n = 48$) and day seven ($n = 6$) of ICU stay respectively (Fig. 2B). During the ICU stay, in three (6.3%) patients eleven platelet transfusion events were reported resulting in the transfusion of fourteen platelet concentrates. Overall, in four (36%) cases, the main reason for transfusion was bleeding, in four (27%) cases the platelet concentrates were transfused prior to an invasive procedure, and in the remaining four (36%) solely the thrombocytopenia was the reason to transfuse. The highest platelet count prior to a platelet transfusion was at 216×10^9/L, received by a patient who used double anti-platelet therapy, and these concentrates were administrated in the operating theatre.

Eight (72.7%) times one unit of platelets was transfused and three (27.3%) times two units were transfused. In all cases where more than one unit was transfused, patients were undergoing a procedure or were bleeding. In three (27.3%) cases, irradiated platelet concentrates were administered. One platelet concentrate (9%) was derived by apheresis and ten concentrates (91%) were pooled buffy coat products, obtained from five different donors. The majority (81.8%) of the platelet concentrates were administered in one single patient.

3.6. Plasma transfusion and coagulation factors

Prothrombin time (PT) remained stable during ICU stay. The median highest PT was 12.0 (10.9–12.5) s at day one and 11.5 (10.8–13.6) s at day seven of ICU stay. 1.7% of the reported PT values were greater than 20 s (Fig. 2C).

A third of the patients had a normal aPTT during their whole ICU stay (aPTT < 33 s). The median aPTT was 26 (24–32) s at day one and 23 (21–26.5) s at day seven of ICU stay (Fig. 2D). In nine (19%) of the patients an aPTT > 40 s was observed at some moment during their stay at the ICU.

Two patients received plasma transfusion during the study period. The mean PT was 12.6 s pre- and 12.6 s post-transfusion. In both cases, no ROTEM was performed prior transfusion. In three (6.3%) different patients, five times tranexamic acid administration was reported. In 80% of these cases, the main reason of administering was bleeding.

Three fibrinogen transfusions were recorded in one single patient, twice prior to an invasive procedure and once when actively bleeding. In one event, ROTEM was performed prior fibrinogen transfusion. In all three events, the fibrinogen target was > 2.0 g/L. Prothrombin complex was transfused once during the study period.

3.7. Patient outcome

Patient outcome was measured at day 28 (Table 3). Median observed ICU length of stay was two days (2–4.25). Six patients (12.2%) were admitted to the ICU for more than seven days. Two patients were still in ICU at 28 days. Mortality in the study cohort was thirteen percent. In patients without any RBC, platelet or plasma transfusion the mortality was 10% versus 25% in the group

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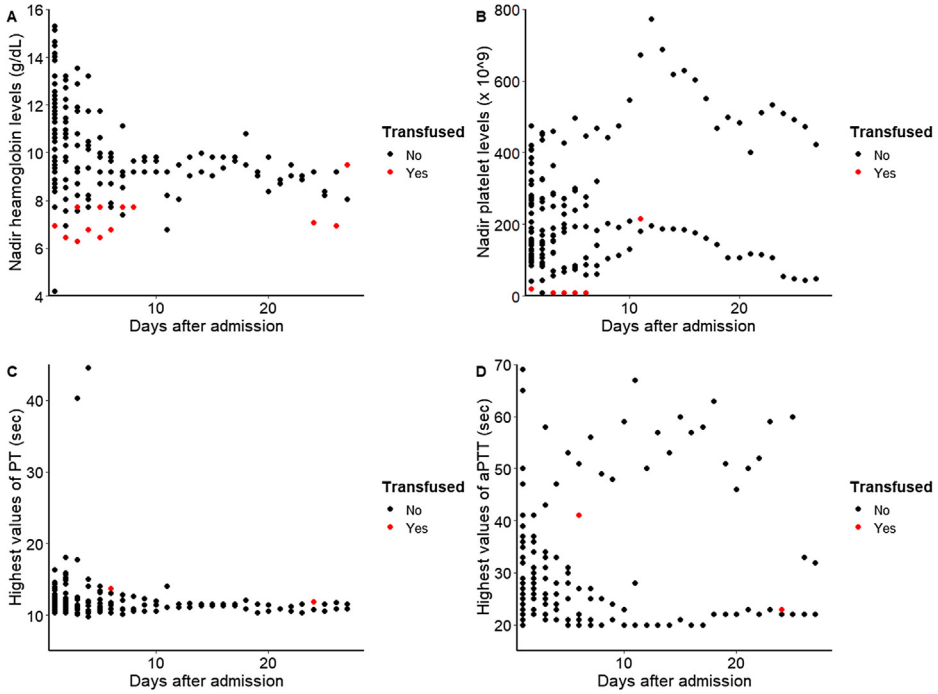

Fig. 2. Levels of haemoglobin (A), platelets(B), PT (C) and aPTT (D) during the 28-day follow-up. Each dot represents a patient. Patients who received a RBC (A), a platelet (B) or a plasma (C-D) transfusion are represented with a red dot.

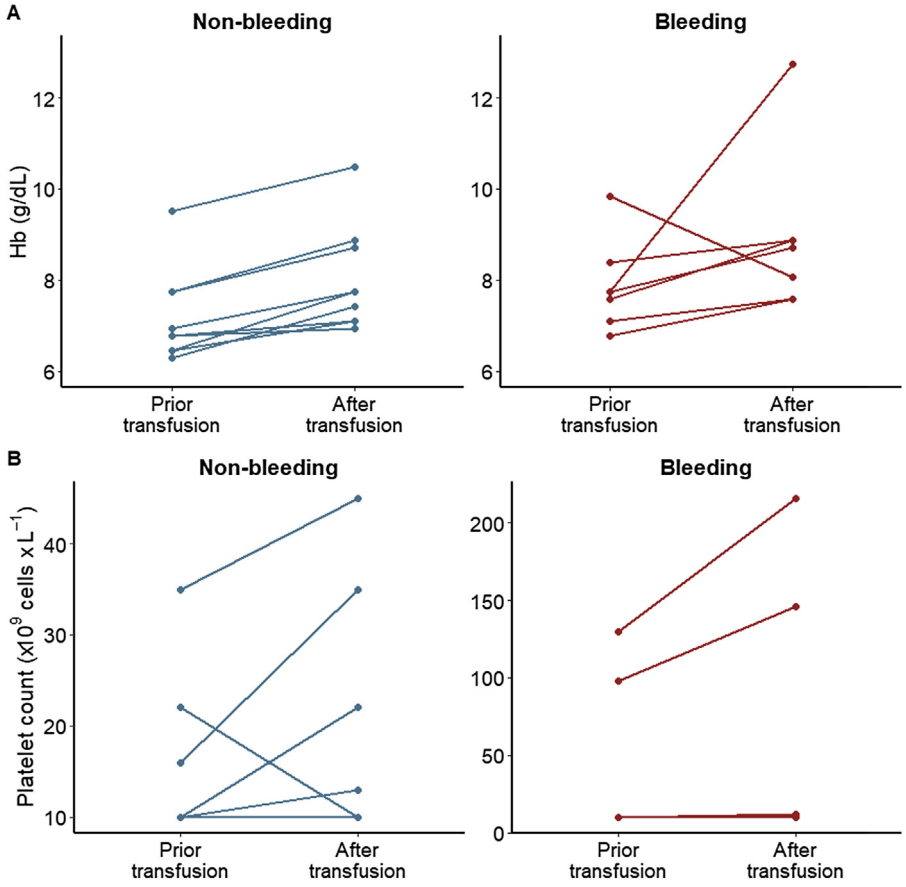

Figure 3. Pre- and post-red blood cell transfusion Hb levels (A) and pre- and post-platelet transfusion count (B) after one or more RBC or platelet transfusions, respectively.

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who did receive one or more RBC, platelet or plasma transfusions ($P = 0.24$).

4. Discussion

In this pilot study, we observed that patients in our ICU were relatively restrictively transfused, and that pre- and post-RBC transfusion Hb levels were similar in bleeding and non-bleeding patients. Furthermore, we showed the feasibility of our study protocol for an international point prevalence study of transfusion practice in ICUs. This study serves as a pilot study, which is ready to be enrolled internationally as an observational cohort study.

In this small population the reported pre-RBC transfusion Hb levels of 7.6 (6.7–7.7) g/dL were lower than a recently published large observational cohort study in the ICU where a mean nadir Hb level on day of transfusion of 8.3 g/dL was reported [2]. Also the proportion of patients transfused with RBCs (12.5%) was lower than in this study where 26.3% received one or more RBC transfusions [2]. This lower proportion could be part of an ongoing downward trend in RBC transfusion, since the proportion of patients who received an RBC transfusion during ICU admittance has been declining the last decade. In 2002, 37.0% of ICU patients was transfused [9], while in 2018 the same research group reported that only 26.3% received RBCs during their ICU stay [2].

Another explanation of the differences with current literature is the large proportion of post cardiothoracic surgery (35%) patients in this patient cohort. These patients were admitted with a relatively high haemoglobin level of 11.8 (10.5–12.1) g/dL and were admitted for a median length of ICU stay of two days, resulting in only one patient in this subpopulation receiving RBC concentrates.

Also, the proportion of patients receiving platelet concentrates in our study was only 6.3% of the patients during ICU admittance, which is slightly less than observed in the United Kingdom in 2012 where 9.0% of a national patient cohort received platelets during ICU stay [3]. Also, in that study more than 40% of the patients who received platelets had a platelet count $\geq 50 \times 10^9$ cells/L [3], while in our study, only 18% of the patients who received platelets had a platelet count $\geq 50 \times 10^9$ cells/L. In addition, all non-bleeding patients who received platelet concentrates prophylactically prior an invasive procedure or without any upcoming procedure had a platelet count of $\leq 50 \times 10^9$ cells/L and $\leq 10 \times 10^9$ cells/L, respectively. Only bleeding patients had a platelet count $\geq 50 \times 10^9$ cells/L prior to transfusion. This is in accordance to our local transfusion guideline. Unnecessary platelet transfusions should be avoided, especially since multiple RCTs in different patient populations have shown an increased mortality in patients transfused with a liberal platelet transfusion strategy [19,20].

While plasma transfusion is possibly beneficial in bleeding patients, plasma transfusion to correct prolonged coagulation time in the absence of bleeding is not recommended [14,15]. This is in accordance with our findings that only patients who were actively bleeding received plasma, but in contrast with a large study in the UK where only a third of the plasma transfusions was given to treat bleeding [21]. Also the proportion of patients of this cohort receiving plasma was two times higher (12.7%) than in our study [4]. The correction of the PT in our patient population was minimal after plasma transfusion.

In this study tranexamic acid was administered five times. Multiple studies showed a reduced need for transfusion during surgery when inhibiting fibrinolysis using tranexamic acid [22]. Also in trauma patients a decreased mortality was found when administering tranexamic acid early after trauma [23]. However, it is unclear how we can extrapolate these results to bleeding patients admitted to the ICU. To our knowledge, RCTs in this patient population comparing tranexamic acid to placebo have never been performed.

The major limitation of this study is the small number of included patients. With only 48 patients in this pilot study, the transfusion numbers are too dependent on a few specific patients; two patients were responsible for 30 transfusion events (79%). Furthermore, this was a single centre study, thus limiting generalizability of the findings.

A large international study is needed to draw valid conclusions on transfusion practices. Ideally, different subpopulations need to be included such as patients with and without bleeding and patients with acute coronary syndrome, brain injury and patients on extracorporeal membrane oxygenation. Current rationale is that these patient categories might need higher Hb levels, while evidence for this is limited. This protocol enables the researchers, when included a sufficient number of patients, to compare transfused and non-transfused patients and examine differences in why certain patients are transfused differently while having similar Hb levels, cell counts and coagulation tests. Numerous studies have studied RBC transfusions in large ICU cohorts, however, international studies examining plasma transfusion, platelet transfusion, and administration of coagulation factors are limited.

The feasibility of this protocol was shown by the acceptable amount of time per patient and number of registered blood product administration. However, based on this pilot study, the study protocol of the international observational cohort study was adjusted. Time consuming data collection that did not result in reliable and useful information was removed from the study protocol, including daily fluid balance and additional questions for the non-transfused patients. Also the workflow of the data collection was improved using an electronic CRF. We expect this to reduce the amount of time to complete the different forms. Also obtaining informed consent might not be necessary in every centre depending on national and local regulations for observational research.

5. Conclusion

In this small patient cohort, a restrictive transfusion strategy was observed. However, due to the small number of inclusions, clinically relevant conclusions cannot be drawn from this study. The feasibility of this protocol was shown in this pilot study and is suitable to compare transfused and non-transfused patients in different subpopulations for different blood products. The current study allowed us to optimize the protocol and as result, this adjusted study protocol will be used in an international multicentre observational point prevalence study. The authors can be contacted for participation in the upcoming international trial.

Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.tracli.2019.09.002.

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