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Concerning one case of rupture of a flow regulator: How patient safety procedures contribute to the correct use of medical devices

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Flow regulators are widely used in hospitals to assist with intravenous (IV) infusion of medication. The rupture of a flow regulator at the base of the clamp was observed during parenteral nutrition. This rupture resulted in fluid leakage and an inlet of air, responsible for an air embolism in a fragile patient who had undergone a bilateral lung transplant. The patient's clinical condition required him to be transferred to a continuous monitoring unit. A serious Adverse Event in Healthcare (AEH) was reported, as well as a medical device vigilance report. A Feedback Committee (FC) was set up and it recommended an audit within the health care departments to study the conditions for use of flow regulators and to propose corrective actions. Despite the technical data sheet of the device not recommending the administration of lipid emulsions and glucose solutions above 10%, the manufacturer's expert report concluded that the mechanical failure could not be linked to the type of solution. However, the audit did reveal a lack of knowledge of certain rules for using this device. The analysis of this AEH is part of the establishment's patient safety procedure. The AEH highlighted a deviation in care concerning the conditions for use of flow regulators, thus resulting in misuse. The collaboration between the various actors involved in the analysis of this AEH led to the implementation of improvement actions on the root causes, related to the lack of information and of training for professionals on correct use of the medical device.

1. Introduction

Flow regulators are single-use medical devices which, when connected to an infusion device, enable to regulate gravity infusion of drugs. Dial flow regulators are made up of a fixed part graduated in millimeters per hour and a moving part with an arrow. To obtain the correct flow rate, the arrow is placed opposite the corresponding graduation (Caruba et al. 2009). These devices are very commonly used by Registered Nurses (RNs) for the reliable administration of drugs, because they are extremely easy to use. Manufacturers provide instructions for their correct use. Despite this, there are numerous materials vigilance reports concerning these devices every year, especially for excessively high rates of infusion (OMEDIT 2011).

This paper describes the management of an Adverse Event in Healthcare (AEH) following the rupture of a flow regulator at the base of the clamp during the IV administration of a parenteral nutrition bag. This rupture resulted in a fluid leak causing an air embolism in a patient, and his subsequent transfer to a Continuous Monitoring Unit (CMU).

2. Investigations and results

This AEH linked to drug administration concerned a 64-year-old patient hospitalized in the Pulmonary Department for immediate post-transplantation monitoring.

2.1. Description of the AEH

In August 2018, the patient was initially hospitalized in the critical care unit following a bilateral lung transplant and was then transferred to the pulmonary unit twenty days before the AEH. His medical history showed tobacco-induced emphysema with bronchial dilation.

At the time of the accident, the RN noted that the parenteral nutrition tubing was disconnected from the right internal jugular Central Venous Catheter (CVC) and there was liquid on the floor. The patient's wife also reported having seen drops of liquid on the floor before she fell asleep in her husband's room.

The patient suffered from dyspnea, with a slight intercostal retraction, but with no reported chest pain. Pulmonary auscultation sounded clear. Oxygen saturation was 88% under 2 L oxygen per minute. The electrocardiogram showed sinus tachycardia with no repolarization disorders. Blood was taken for tests and for arterial-blood gas analysis.

Given the suspicion of an air embolism, a hyperbaric chamber was ordered. In the meantime, the patient was placed on his left side with monitoring for any neurological signs. Then, after cleaning out the CVC tubing as much as possible, the patient was given oxygen treatment with a high concentration mask at a flow of 15 L/min, combined with vascular filling using 250 mL 0.9% sodium chloride and blood pressure monitoring.

Given the absence of neurological signs and the patient's good response to oxygen therapy, hyperbaric oxygen therapy was no longer considered necessary. The patient was subsequently transferred to a CMU for 24 h of reinforced monitoring.

This serious AEH led the department in question to report it via the hazard management program BlueMedi®.

2.2. AEH report

Reporting this AEH resulted in a certain number of actions being taken. A materials vigilance report was immediately sent to the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM; French National Agency for Medecine and Health Product Safety) and to the manufacturer to carry out investigations on the medical device. Simultaneously, a literary review on the use

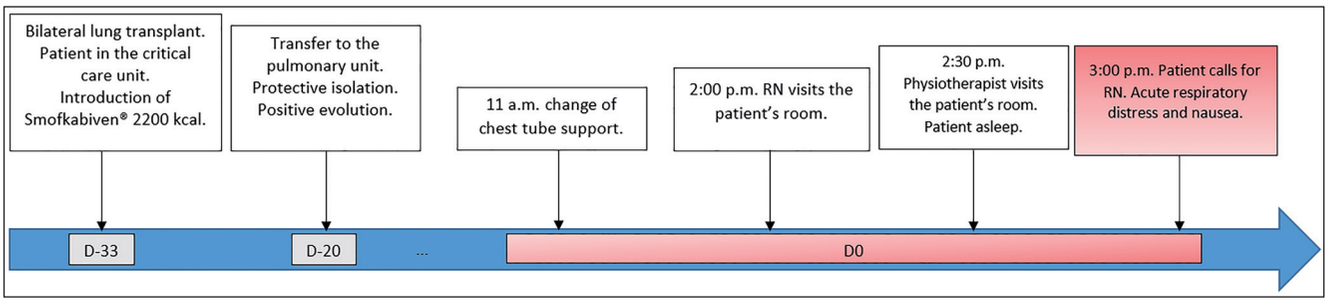


Fig. 1: Description of the AEH

of flow regulators was carried out. This review enabled to go back over the manufacturer's recommendations and to underline the requirement that pharmacists should be involved in the correct use of this type of medical device.

2.3. Feedback Committee (FC)

Fifteen days after the AEH, a FC was held in the department, made up of senior and junior doctors, the department's executive nurse and RNs, pharmacists, resident pharmacists and also members of the hospital's health and safety unit. This AEH was analyzed using a time line allowing each participant to understand the chronological order of the events and of patient care, as well as identified deviations from practice (Fig. 1). This time line was drawn up according to investigations on the staff members concerned and a review of the elements in the patient's medical file.

2.4. Data collection

Using data found in the literature and in response to improvement measures validated by the FC, the pharmacists drew up an audit chart on the use of flow regulators (Fig. 2). This chart included nine items: manufacturer's recommendations, choice of use, knowledge about the sterility of the medical device, problems encountered during use, and whether it was necessary or not to be given information to ensure the correct use of flow regulators (Djian et al. 2008).

As a supplement, figures for the consumption of this medical device during 2018 were extracted using the Pharma® prescription and inventory management software, enabling to target the departments which used the most flow regulators. Audit results were colligated and analyzed using Excel®.

2.5. Manufacturer's laboratory analysis

Examination of the medical device showed the defect mentioned in the report, i.e. the flow regulator was split in two at the base of the clamp (Fig. 3). This rupture was not linked to the type of fluid infused, as the place where it had mechanically broken was not in contact with the liquid being infused. The cause of this mechanical rupture therefore remains unknown. The manufacturer Cair LGL confirmed that there had been no other reports of this type for this reference DF050, without however stating which period of time this referred to.

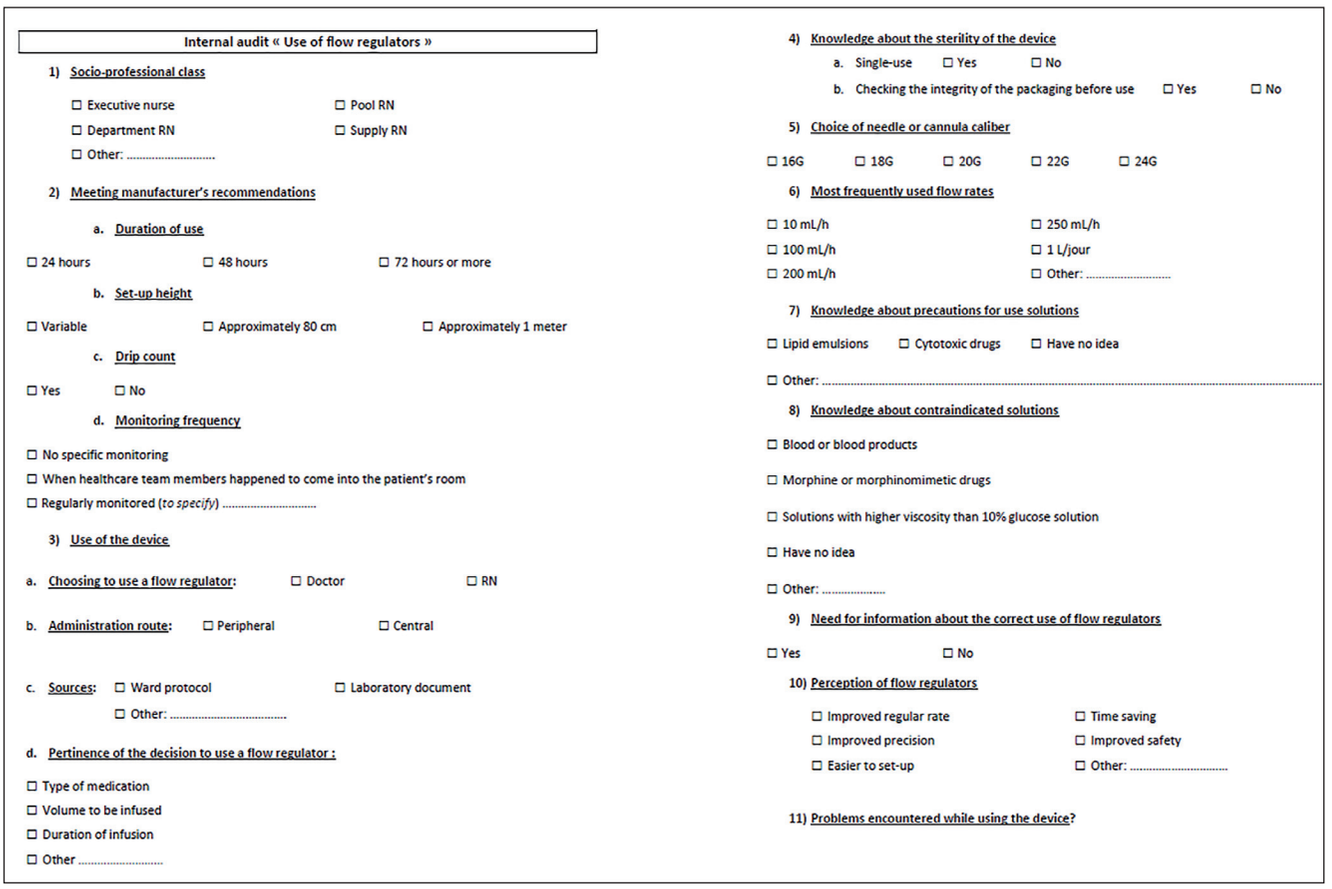
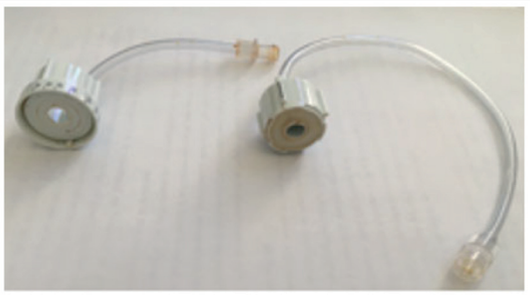
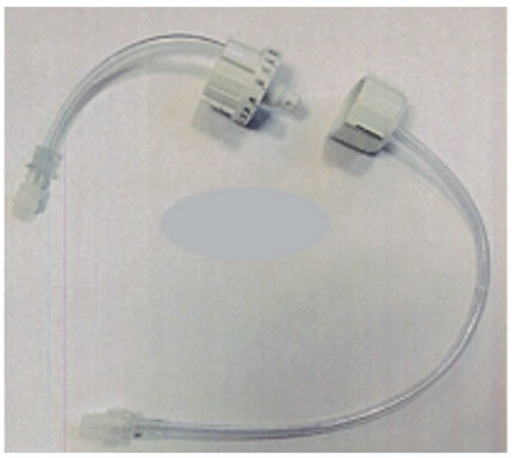


Fig. 2: Audit of practices in the health care departments



Flow regulator found during the AEH



Functional flow regulator, split for comparison

Fig. 3: Examination of the device

2.6. FC: Analysis

The flow regulator used for the infusion of a parenteral nutrition bag was found by the paramedical team completely split into two parts: one linked up to the CVC line, the other joined to the parenteral nutrition bag which had emptied itself onto the floor.

The immediate cause retained on the time line is involuntary use of an unsuitable device for the administration of parenteral nutrition. Three root causes for this misuse were identified, one linked to the medical team: a lack of information on the use of flow regulators, and two linked to the material: a probable defect of the flow regulator and the lack of infusion pumps in the department in question, despite the fact that many patients are on parenteral nutrition or long-term IV therapy.

2.7. FC: Improvement measures

Four actions for improvement were found from the analysis, they concerned the material, improvement of practices and of communication. The service sent the biomedical department a request for infusion pumps to be made available or bought, especially to ensure safe administration of parenteral nutrition bags. An internal audit concerning the use of flow regulators was commissioned for all of the departments who used this type of medical device, resulting in an information sheet recalling instructions for use of flow regulators and the distribution of this information in staff meetings.

2.8. Descriptive analysis of the audit

The 19 care units belonging to 5 different departments, including the pulmonary unit, using the most flow regulators were audited over 3 months (Table). For each of these units, several agents were independently questioned. Each personal interview was led by a student in pharmacy, accompanied by the referring resident pharmacist for the unit. The socio-professional distribution of the 70 agents audited included 3 executive nurses, 50 RNs in the department, 3 pool RNs, 1 supply RN and 13 resident doctors or student nurses (Fig. 4).

Table: Number of people audited and annual consumption of flow regulators in 2018 per department

Department	Number of people audited	Quantity of flow regulators used in 2018
Medicine	33	11 946
Intensive care	6	7 150
Ambulatory and Very Short Stays	15	6 700
Surgery	12	6 600
Cardiology intensive care	4	3 950
Total	**70**	**36 346**

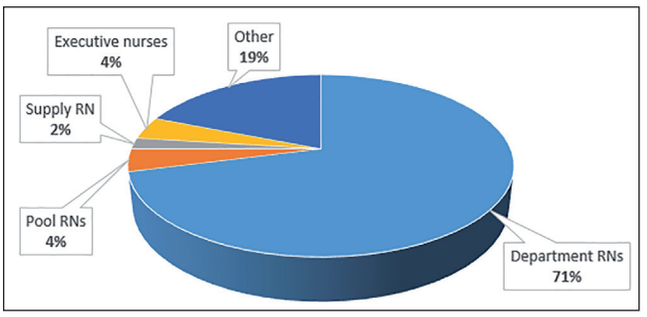


Fig. 4: Socio-professional distribution of audited staff members

2.8.1. Choosing to use a flow regulator

In 96% of cases (n=67), it was the RN who decided to use a flow regulator. Doctors only made this decision in 4% of cases. All of the staff audited knew that flow regulators could be used for peripheral IV therapy, but 41% (n=29) of the members audited thought that they could not be used with a CVC.

2.8.2. Pertinence of the decision to use a flow regulator

The choice of using a flow regulator depends on the type of medication, the volume to be infused and/or the duration of infusion. Only one of these parameters was taken into consideration by 52% of users (n=37). This was infusion volume in 30% of cases (n=21), duration of infusion in 14% of cases (n=10), and the type of medication in 8% of cases (n=6). All three parameters were only taken into consideration by 19% of the members interviewed (n=13). 26% (n=18) of health care providers considered that only two parameters were necessary when deciding to use a flow regulator. These parameters were: infusion volume combined with duration of infusion in 16% of cases (n=11), type of medication and duration of infusion in 7% of cases (n=5), and type of medication and infusion volume in 3% of cases (n=2). For the remaining 3% (n=2), other parameters were taken into consideration, with no further information.

2.8.3. Correct use of the device

Professionals used different sources to ensure the correct use of these devices. Most often, i.e. 16% (n=11) of health care providers obtained information from the pharmacy. The others consulted different documents. In 7% of cases (n=5) this was the flow regulator information sheet, in 6% of cases (n=4) it was a ward protocol, and in another 6% of cases it was a laboratory document. One health care provider (1%) followed the procedures available in the facility's computer document management system, and another health care provider (1%) used internet search engines. Therefore,

63% of health care providers interviewed (n=44), consulted neither information sheets nor reference documents to ensure that the flow regulator was used correctly (Fig. 5).

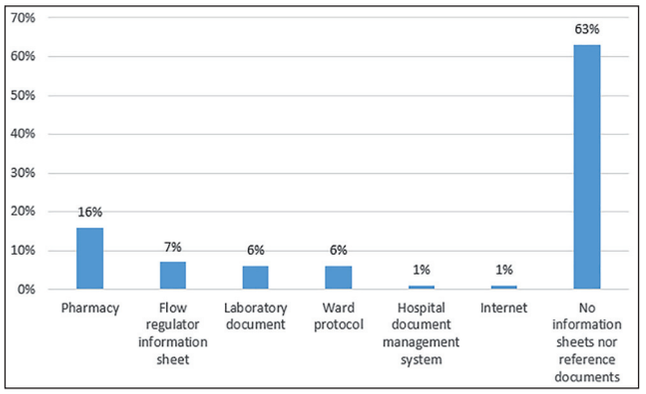


Fig. 5: Sources used for correct use of the device

2.8.4. *Need for information about the correct use of flow regulators*

69% of people interviewed (n=48) felt that they needed training about the correct use of flow regulators.

2.8.5. *Meeting manufacturer's recommendations*

Half of the staff members (n=35) questioned for the audit stated that they used the same flow regulator for 72 hours or more, whereas the manufacturer recommended a maximum of 48 hour's use. 20% (n=14) changed the flow regulator every 24 hours and 30% (n=21) used it for 48 hours, i.e. 50% of correct use for the item "duration of use" (Fig. 6).

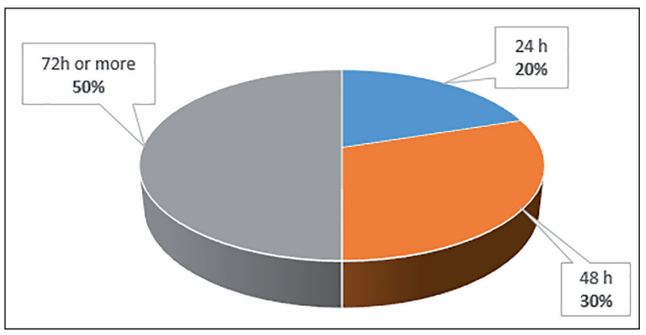


Fig. 6: Duration of use for flow regulators

Set-up height of the device was variable in 44% of cases (n=31), whereas the device is calibrated for a height between 80 and 100 cm. The majority of staff members, i.e. 49% (n=34), set it up at 80 cm, and at approximately 1 meter for 7% (n=5) of cases, i.e. 56% of correct use for the item "set-up height" (Fig. 7).
Drip count to check the selected flow rate was only done by 29% (n=20) of members audited.
The frequency of the flow rate was mainly monitored when health-care team members happened to come into the patient's room, in 57% of cases (n=40). It was regularly monitored in 30% of cases (n=21) and there was no specific monitoring in 13% of cases (n=9), whereas it is recommended to check the flow rate at least every two hours.

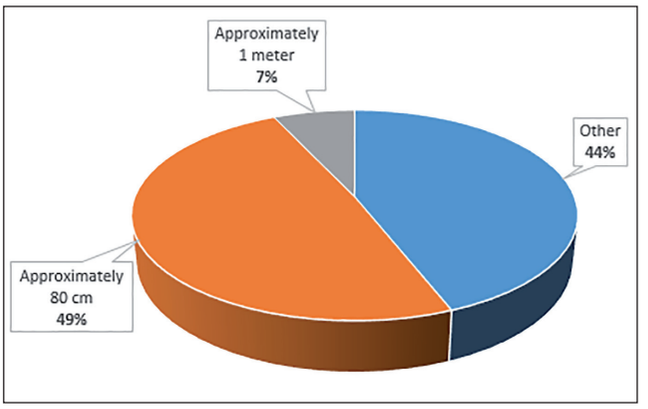


Fig. 7: Set-up height for flow regulators

2.8.6. *Knowledge about the sterility of the device*

All of the staff members audited knew that flow regulators were sterile, single-use medical devices, and package integrity was reportedly checked in 100% of cases.

2.8.7. *Material and flow rate*

Each member of staff had needle or cannula calibers they preferred (n=109). The flow regulator manufacturer recommended use of at least a 22 Gauge catheter or less. Calibers chosen were: 16 Gauge in 4% of cases (n=4), 18 Gauge in 43% of cases (n=47), 20 Gauge in 23% of cases (n=25), 22 Gauge in 20% of cases (n=22) and finally 24 Gauge in 10% of cases (n=11), i.e. 90% of correct use (Fig. 8).
The most frequently used flow rates used with flow regulators were also noted. These were extremely varied and yielded 105 answers. In 51% of cases (n=54) flow regulators were used at an IV flow rate of 1 L/day or 40 mL/h (Fig. 9).

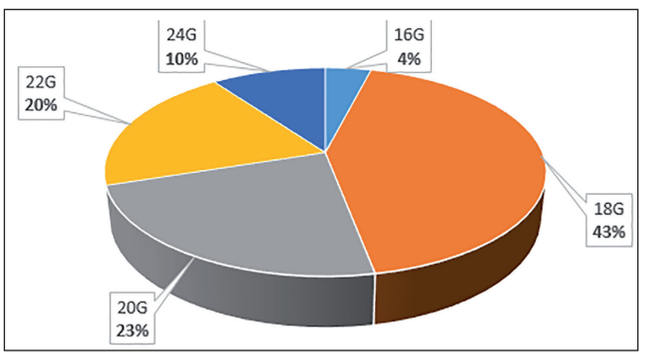


Fig. 8: Choice of needle or cannula caliber

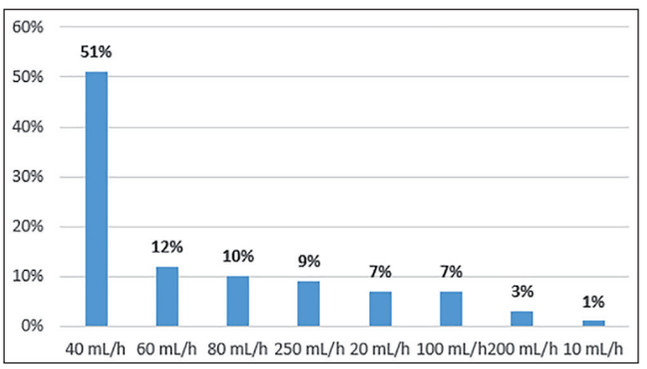


Fig. 9: Most frequently used flow rates

2.8.8. *Knowledge about contraindicated solutions or precautions for use*

Knowledge varied on solutions that were contraindicated when using flow regulators. 73% of health care providers (n=51) did not use flow regulators with blood or blood products. 57% (n=40) did not use them with morphine or morphinomimetic drugs. 14 % (n=10) believed that solutions with a higher viscosity than 10% glucose solution were contraindicated. 21% (n=15) of the staff members who were audited stated that they knew of no contraindications for the use of flow regulators.

Knowledge was poor on solutions requiring precautions for use with this type of device. Indeed, 96% (n=67) of care workers did not know these precautions for use. 3% (n=2) had some notions concerning cytotoxic drugs, and 1% (n=1) concerning lipid emulsions.

2.8.9. *Perception of flow regulators*

172 answers were given to the question about the perception of flow regulators, these highlighted the multiple advantages for medical teams which potentially encouraged a false sense of safety concerning their use. In 66% of cases (n=46), they were identified as time saving. In 57% of cases (n=40), health care providers thought that using flow regulators improved safety. In 53% of cases (n=37), the people questioned considered that flow regulators gave

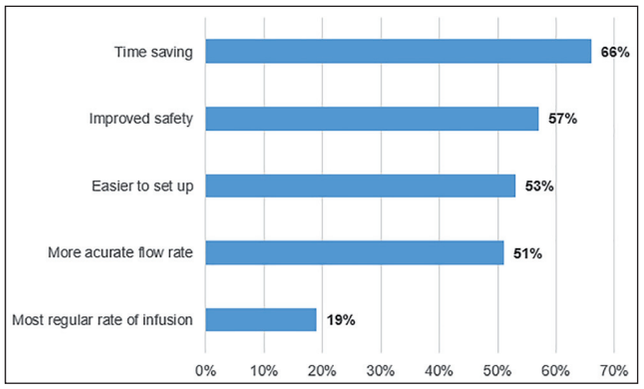


Fig. 10: Perception of flow regulators

a more accurate flow rate than other available devices. In 51% of cases (n=36), flow regulators were stated as being easier to set up than other devices. Finally, in 19% of cases (n=13), health care providers thought that flow regulators were the device giving the most regular rate of infusion (Fig. 10).

2.8.10. *Problems encountered while using the device*

The large majority of staff members audited, i.e. 87 % (n=61), had not experienced any particular problems using flow regulators, 7% (n=5) mentioned faulty devices and 6% (n=4) reported issues with flow rate accuracy.

3. Discussion

This targeted audit revealed a large variety of reasons for using flow regulators and of ways they were used. Guidelines for good practice were not entirely respected for the points given below.

3.1. *Set-up height for flow regulators*

According to Poiseuille's law, gravity infusion depends on four parameters: pressure gradient across the tubing, viscosity of the fluid, and diameter and length of tubing. For example, for two identical infusions, the pressure gradient depends on the point in the procedure and the patient. Faced with this knowledge, the manufacturer calibrates the accuracy of the regulator on the flow rate of a solution of distilled water or of 5% glucose placed at a height of 80 to 100 cm, with tubing connected to a 20 Gauge catheter at least. In this case the accuracy of a flow regulator is estimated to be approximately between 8 and 12% (CAIR 2021a). Furthermore, the study by Ténière et al. (2015) carried out at the Civil Hospices in Lyon showed that the graduations on the dials of flow regulators did not match observed flow rates, with variations between the number on the dial and the actual flow rate reaching up to 20%. The study by Loner et al. (2018) showed that significant deviations from expected volume were observed across multiple intravenous infusion flow regulators tested in a laboratory environment. Our study confirms a certain number of critical points in the use of flow regulators. The manufacturer of the flow regulator currently referenced, states that the infusion bag or container must be one meter higher than the puncture site. However, this height was only respected in 7% of cases.

3.2. *Frequency of changing flow regulator*

The frequency at which flow regulators should be changed was not known by staff members, as 50% stated that they used them for 72 hours or more, whereas the manufacturer recommends changing them every 48 hours.

3.3. *Knowledge about contraindicated solutions or precautions for use*

The use of flow regulators is contraindicated for the administration of blood or blood products and for morphine or morphinomimetic drugs. It is also not recommended for use with glucose solutions higher than 10%, lipid emulsions and cytotoxic drugs for which variations in flow rate are potentially harmful (CAIR 2021b). This AEH occurred during the infusion of a solution of Smofkabiven® 2200 kcal which is both a lipid emulsion and a fluid with a higher viscosity than a 10% glucose solution. Contrary to manufacturer's recommendations, the majority of health care providers did not first consider the type of solution to be infused, as one third of the people audited said that they considered infusion volume first. Despite these observations, in 63% of the cases in this study, the medical team did not refer to supporting documents or protocols when using flow regulators, this may be justified by the lack of or the unsuitability of reference documents, or by the fact that IV therapy is routine practice in these departments. However, the loss of accuracy shown by Poiseuille's law explains why flow regulator manufacturers give numerous recommendations. This was also shown in the study by Le Reste et al. (2016). Effectively, RNs seem to rely on what they learned from their initial training and training courses without referring to information sheets or to recommendations for use of the medical device in question. Our study revealed a lack of knowledge concerning contraindications and precautions for use, or non compliance, despite the broad use of flow regulators, which was also observed in a study by Le Bouar et al. (2002).

3.4. *Choice of needle or cannula caliber*

This type of regulator is calibrated for the use of short or central cannulae, with a caliber of 22 Gauge or higher. However, 41% of staff members audited thought that this device should not be used with a central catheter and 10% used it with cannula calibers of 22 Gauge or less.

3.5. *Regulating flow rate and monitoring*

The flow rate of 5 to 250 mL/h, recommended by the manufacturer, is compulsory when using a flow regulator. Flow rate must be checked by a drip count upon set-up and the medical team should monitor this every two hours. Despite these instructions for use, 71% of the staff members who were audited considered that flow regulators could be trusted and did not perform a drip count to regulate and check the flow rate. Furthermore, 70% of staff members did not monitor the flow rate during IV therapy or only did so infrequently. These results corroborate those from

the study by Guenfoudi-Roullaud et al. (2000) who showed that flow regulators were considered to be trustworthy by 73% of RNs. Moreover, adjusting the flow rate using a drip count is simple and can prevent a majority of errors in flow rate that may jeopardize the efficacy of treatment and the patient's safety. This therefore represents a high level of variability, because it depends on the professional experience of the staff handling the device. The time factor should also be taken into account, as RNs lack time to carry out their multiple tasks which can lead to involuntary but potentially critical misuse (Caruba et al. 2009). Data found in literature recommended to readjust the flow rate after 15 min then regular monitoring every 4 h to ensure a stable rate, whereas the currently referenced manufacturer recommends monitoring every 2 h (Simon et al. 2011; Ténière et al. 2015). Knowledge and skills of the medical team and especially RNs are extremely important in IV therapy and the correct use of medical devices, even more so given that it is usually them who decide whether to use a flow regulator or not (Infusion Nurses Society 2011). IV therapy has been trivialized as RNs use it several times a day. This generalization, combined with poor knowledge on the use of flow regulators, can result in serious AEH, like the one analyzed in this study, that may be life-threatening for patients (Brun et al. 2007a; Cabelguenne et al. 2004). Nevertheless, the staff members audited perceived flow regulators as being positive because of their claimed multiple advantages. This shows that the users did not consider the lack of accuracy in flow rate, shown in the study by Djian et al. (2008). This type of device can sometimes mislead users towards a false sense of security. It is the regulation of the flow rate however, that is an essential element in controlling the speed of administration of a drug in IV therapy, and consequently the volume and quantity delivered to the patient.

3.6. Correct use of medical devices

According to data found in literature, this misuse of flow regulators and the medical team's lack of knowledge have also been reported in other hospital centers who also proposed recommendations for the correct use of these medical devices (Bernard et al. 2006; Brun et al. 2007a; Demore et al. 1994; Djian et al. 2008). Our study was performed on the largest consumers of flow regulators in the hospital center. It would also be interesting to obtain results from the departments which use less flow regulators.

Compliance with manufacturer recommendations is essential for the correct use of a medical device, as well as being necessary for the device to maintain high performance. Furthermore, correct use is critical to ensure therapeutic efficacy of the drug administered and consequently patient safety (Brun et al. 2007b). Medical staff seem to pay less attention to medical devices than to drugs. However, a lack of comprehension concerning the use and correct use of a medical device in IV therapy can indirectly lead to medication errors. One study showed that use of a medical device in IV therapy caused three times more risk of error than other categories of medical device (Le Reste et al. 2016).

The people audited mainly felt that there was a need for training in the use of medical devices. It is one of the hospital pharmacist's tasks to provide information on the correct use of sterile medical devices (Brun et al. 2007b; Ministère de l'emploi et de la solidarité 2000). An information notice recalling the correct use of flow regulators for care units is currently being finished, as well as a training course schedule for the medical staff in departments where they are used. Subsequent reassessment via another audit is scheduled.

IV therapy with other types of medication or in conditions that differ from those recommended by flow regulator manufacturers, require the use of other active devices: volumetric infusion pumps and electric syringe pumps. Design and performance specifications of both of these types of device meet French standards.

Volumetric infusion pumps have an accuracy of approximately 5% and are used for volumes above 60 mL. They meet the NF S90-250 standard (Association française de normalisation 1990). They are active medical devices as opposed to flow regulators which are passive. Flow regulation is ensured by an electronic system and any dysfunction sets off an alarm. The unit cost of these devices is, however, higher (Caruba et al. 2009).

Syringe pumps have an approximate accuracy of 3% and are used for volumes below 60 mL. They meet the NF S90-251 French national standard (Association française de normalisation 1986).

Therefore the choice of an active or passive device depends on various parameters, including the type of medication to be infused, its volume and the duration of administration (Djian et al. 2008; Farrington et al. 1988; Ténière et al. 2015). The absence of syringe or infusion pumps in a department may lead to inappropriate use of flow regulators. An active medical device is however necessary for the administration of any narrow therapeutic range drugs. Indeed, the study by Horrow *et al*. showed that variations between displayed flow rates and actual flow rates could reach 20%, especially for low rates (Horrow et al. 1987). One study carried out at the European Hospital Georges Pompidou in Paris led to the withdrawal of flow regulators from the therapy handbook and to an increase in the number of programmable pumps made available (Brun et al. 2007b; Djian et al. 2008). Equipping the hospital in active infusion devices is therefore an option to be considered in collaboration with the biomedical department, and the National Patient Safety Agency in the United Kingdom has recommended that an adequate number of pumps should be made available for medical teams (NHS 2019). Given the cost of these devices and of consumables compared to that of passive devices, it is necessary to define the conditions for use, especially according to the type of medication.

3.7. Conclusion

The analysis of this AEH associated with a medical device commonly used to administer medication is pertinent as this type of adverse event (AE) is quite an emblematic risk-purporting event; it often remains unnoticed but can, like prescription errors, cause serious AEs such as the air embolism reported in this study. This analysis is part of the facility's patient safety procedure. The collaboration between different partners involved in this AEH made it possible to propose actions for improvement. The conclusions of our audits corroborate with those of other investigations carried out in other hospital centers and published in scientific literature. They allowed us to target deviations from practice better and thus to devise improvements in the correct use of medical devices within our hospital center. The action plan focused on theory and practical training for RNs concerning administration, on awareness for healthcare professionals and on risk management culture.

The misuse brought to light in this study shows that flow regulators can mislead health care providers towards a false sense of safety by trusting flow rate regulation even though manufacturer recommendations are not respected. This reveals a lack of training, of information and of knowledge concerning the use of these devices on behalf of the medical and paramedical teams.

Our study confirms that the interest the medical staff have in this type of material relies on the fact that it enables to define a flow rate for IV infusion and maintain it throughout the duration of IV administration. Correct use of a drug necessarily involves the correct use of medical devices used for IV infusion. In compliance with the French law of December 8, 1992 concerning Hospital Pharmacies, one of the pharmacist's tasks is to "lead or participate in information campaigns on drugs, materials, products or objects, as well as in any actions of promotion or assessment of their correct use" (Ministère de l'Emploi et de l'Action humanitaire 1992).

Actions for improvement have been implemented. Their efficacy will be assessed using indicators for the knowledge of healthcare professionals and the application of good practices. Professional practices will be reassessed once information has been distributed and staff have undergone training. In parallel, the impact on the consumption of this type of device will also be analyzed.

Conflicts of interest: Non reported.

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