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Procedures Performed by Advanced Practice Providers Compared With Medical Residents in the ICU: A Prospective Observational Study

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Objective: To assess the frequency and safety of procedures performed by advanced practice providers and medical residents in a mixed-bed ICU.

Design: A prospective observational study where consecutive invasive procedures were studied over a period of 1 year and 8 months. The interventions were registered anonymously in an online database. Endpoints were success rate at first attempt, number of attempts, complications, level of supervision, and teamwork.

Setting: A 33-bedded mixed ICU.

Subjects: Advanced practice providers and medical residents.

Interventions: Registration of the performance of tracheal intubation, central venous and arterial access, tube thoracostomies, interhospital transportation, and electrical cardioversion.

Measurement and Main Results: A full-time advanced practice provider performed an average of 168 procedures and a medical resident an average of 68. The advanced practice provider inserted significant more radial, brachial, and femoral artery catheters (66% vs 74%, p = 0.17; 15% vs 12%, p = 0.14; 18% vs 14%, p = 0.14, respectively). The median number of attempts needed to successfully insert

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an arterial catheter was lower, and the success rate at first attempt was higher in the group treated by advanced practice providers (1.30 [interguartile range, 1-1.82] vs 1.53 [interguartile range, 1-2.27], p < 0.0001; and 71% vs 54%, p < 0.0001). The advanced practice providers inserted more central venous catheters (247 vs 177) with a lower median number of attempts (1.20 [interquartile range, 1-1.71] vs 1.33 [interquartile range, 1-1.86]) and a higher success rate at first attempt (81% vs 70%; p < 0.005). The number of intubations by advanced practice providers was 143 and by medical residents was 115 with more supervision by the advanced practice provider (10% vs 0%; p = 0.01). Team performance, as reported by nursing staff, was higher during advanced practice provider procedures compared with medical resident procedures (median, 4.85 [interquartile range, 4.85-5] vs 4.73 [interguartile range, 4.22-5]). Other procedures were also more often performed by advanced practice providers. The complication rate in the advanced practice provider-treated patient group was lower than that in the medical resident group.

Conclusions: Advanced practice providers in critical care performed procedures safe and effectively when compared with medical residents. Advanced practice providers appear to be a valuable addition to the professional staff in critical care when it comes to invasive procedures. **Key Words:** advanced practice provider; critical care; intensive care; intubation; invasive procedures

The advanced practice provider (APP) increasingly contributes to the clinical expertise in the area of critical care. They provide timely and high-quality care for the critically ill patient. Although a fair amount of articles about this relatively new profession have been published, some critical care organizations consider this evidence to be too limited to support the widespread implementation of APPs (1, 2). Besides this, there is a certain global unawareness among critical care professionals about the full potential and valuable contribution of the APP to critical care (3).

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According to the literature, APPs are embedded in critical care areas in several countries including the United States (4–8).

The APP in critical care can perform multiple life-saving tasks as part of a multiprofessional team and can even extend coverage of critical care expertise in critical access areas where physician coverage is limited. Therefore, cost-efficiency or a shortage of critical care physicians in several countries might lead to an increased demand of APPs (9, 10). Because of the increasing utilization of APPs in critical care, it is important to clearly define their role and investigate areas where these professionals provide high-quality care.

One of the aspects of this high-quality care is performing procedures on the ICU. To measure and establish the quality of these procedures, we performed a prospective observational study in which we compared the quality of ICU procedures performed by APPs to the procedures performed by medical residents (MRs).

METHODS

Setting

This study was performed in a 33-bedded mixed medical, surgical, and cardiothoracic ICU in the Catharina Hospital in Eindhoven, The Netherlands. This is a major teaching hospital in the Netherlands, providing a wide variety of clinical care including cardiac surgery. The medical staff of the ICU consists of intensivists supported by MRs and APPs. Some residents have a rotating schedule of 3 or 4 months in which ICU experience is obtained for their specialist training and some residents remain longer for a maximum of 1.5 years. The weekly required working hours and night shifts for residents and APPs on our ICU are equal and are limited to 38 hours per week according to Dutch legislation and local agreements.

APPs

The APPs are qualified as physician assistants (PAs) and followed a training of 2.5 years with theoretical and practical examinations in the medical domain to obtain a masters degree. ICU experience is acquired on the job. All PAs have an ICU nursing background. In the area of critical care, the PAs are licensed to diagnose and treat patients autonomously together with other professionals. Accreditation has to be obtained during 5-year intervals.

MRs

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The different specialty tracks of the MRs are coming from are: surgery, internal medicine, cardiology, and pulmonology.

Study Design

The study was planned over a period of 1 year and 8 months. All consecutive procedures performed by APPs and MRs were prospectively monitored and analyzed. The ethics committee and local institutional review board reviewed and approved the study.

Data Collection and Procedures. A registration website with restricted access was developed for all procedures. A database with standardized forms was created with mixed limited choice and free-text answers. For each procedure, the APPs or MRs name, date, supervising clinician, and registered nurse (RN) were registered. In addition, the ICU nurse assisting with the procedure was instructed to score team performance and patient communication in the same form. Team performance was graded by the RN on a performance scale from 1 to 5: 1 being poor and 5 being optimal team performance. The scoring was a subjective opinion about the situation, which was not anonymous. APPs cross-checked whether procedures of either APPs or MRs were registered.

Inclusion criteria. All procedures performed by APPs and MRs are stated below.

Exclusion criteria. None.

Arterial Catheters. For all arterial catheters, the anatomic location of artery, type of catheter, the use of ultrasound, presence of vasopressors, the mean arterial blood pressure of the patient during the procedure, palpability of artery, number of attempts, success rate and earlier attempts by another APP or MR, and the Acute Physiology and Chronic Health Evaluation (APACHE) score were registered.

The following complications of arterial line insertion were recorded: hematoma (subcutaneous containment of bleeding), bleeding (macroscopic bleeding), and the inability to insert a guide wire in case of using the Seldinger technique. In all cases, a 20-Birmingham gauge (G) radial artery catheter was used with or without Seldinger technique (Becton Dickinson, Franklin Lakes, NJ) or an 18G femoral artery catheter with Seldinger technique was used (Arrow Teleflex, Wayne, PA).

Central Venous Catheters. For all central venous catheters, the anatomic location, type of catheter, the use of ultrasound, number of attempts, success rate, and earlier attempts by another APP or MR were registered.

Regarding the complications, arterial puncture, bleeding (hemothorax), hydrothorax, and pneumothorax (subcutaneous emphysema was also regarded as pneumothorax) were registered and labeled as major complications. Guide wire insertion problems, introducer problems, local hematomas, and other technical problems with easy solutions were registered as minor problems. Due to institutional processes regarding monitoring for central line infection, these data were not collected through our website registration system. However, these data were obtained through a separate system and checked against our registration. Infections occurring after 1 week were excluded from this study due to possible confounding factors outside of insertion techniques. Correct placement of the catheter was obtained after review of the chest x-ray. In all cases, an 8.5F triple-lumen catheter (Arrow Teleflex) or a 11F femoral dialysis catheter or a 14F soft tip dialysis catheter for jugular insertion was used (Dirinco, Oss, The Netherlands).

Intubations. All intubations were prepared according to a preintubation checklist. This checklist includes the technical devices that must be present, the back-up plan in case of an "unable to intubate" scenario, and the instructions to the team regarding the procedure and the back-up plan. The registration noted all medications that were used, the reason for intubation, the type of laryngoscope, and the Cormack-Lehane classification (11).

Multiple attempts, esophageal placement of the tube, aspiration, resuscitation, and other relative complications were registered as complications including tube migration, change of laryngoscope, and intervention by supervising clinician.

Residents and APPs were allowed to perform the intubations without direct supervision after an authorization from the ICU management. In all cases, a 7- to 8.5-mm oral/nasal cuffed tube was used (Covidien, Mansfield, MA).

Chest Tube Insertion. The registration comprised the location, the kind of diagnostic procedure (pleural drainage or tube insertion), the type of chest tube that was used, and complications. Because the internship of the resident is relatively short (minimum 4 mo and maximum 1.5 yr) in comparison to APPs and the amount of procedures is limited, only absolute numbers are presented, and no *p* values are given.

Transportation. This registry comprised intrahospital transportation with medical accompaniment, for example, a CT scan with patients on mechanical ventilation. The transportation to and from the operating theater is excluded because an escort is provided by the anesthesiologist. Because the internship of the resident is relatively short (minimum 4 mo and maximum 1.5 yr) in comparison to APPs and the amount of procedures is limited, only absolute numbers are presented, and no *p* values are given.

Electrical Cardioversion of Rhythms. Baseline registration and complications are registered. Because the internship of the resident is relatively short (minimum 4 mo and maximum 1.5 yr) in comparison to APPs and the amount of procedures is limited, only absolute numbers are presented, and no *p* values are given.

Tracheostomy Cannula Exchange. Baseline registration and complications were registered.

Supervision

When supervision was required, a physician was present and supervised the procedure by verbally guiding the MR or APP or by providing hands-on supervision. Supervision provided by the APP to MRs or colleagues was performed in the same way. MRs deemed qualified by the intensivist to perform a procedure alone were also permitted to supervise other procedures.



Data are described as numbers and percentages or given as a mean with sp. In case of skewed distribution, the median and interquartile range (IQR) are reported. APPs and residents are compared as independent groups with the chi-square test, all with Yates Continuity Correction (large samples) for ordinal or dichotomous data and with the Fisher exact test for small samples. The Mann-Whitney U test was used for continuous data. A two-sided p value lower than 0.05 is considered as statistically significant. All statistical analyses were performed with SPSS version 25 (IBM, Armonk, NY). In the subdivision complications, p values were only calculated when there were enough events to calculate any clinically relevant difference.

RESULTS

In 2017, five APPs covering a total of 4.84 full-time equivalent (FTE) and 10 MRs covering a total of 9.54 FTE performed all procedures. In 2018, these FTEs were 5.59 and 9.56, respectively. Because most MRs did not stay the entire year and one new APP started during the study, the FTEs differed during the 2 years and were not equal round numbers. The average experience of the APPs working on the ICU during this study was 6.75 years. The experience years are presented in **Figure 1**. The two most inexperience of all MRs was less than 1-year ICU experience. The ICU experience of all MRs was less than 2 years although residents from the surgical and cardiologic specialties often had some experience in procedures like intravascular catheterization. The residents from the department of internal medicine occasionally gained experience during earlier internships on the ICU.

The total number of invasive procedures (arterial catheters, central catheters, and intubations) performed by APPs was 868 and by MRs was 647. This resulted in 168 procedures per FTE APP and 68 procedures per FTE MR.

Arterial Access

The total number of arterial invasive cannulations was 835; 478 performed by APPs and 355 by MRs (Table 1), 90 cannulations per FTE APP and 37 cannulations per FTE MR. The results are summarized in Table 1. The number of attempts before success in the APP group was median 1.30 (IQR, 1.0-1.82) and in the MR group was median 1.53 (IQR, 1.0-2.27) (*p* < 0.001). The patients treated by APPs used significantly more vasopressors (p = 0.04), they had a significantly lower systolic blood pressure (p = 0.04), and the arteries of their group of patients were significantly less palpable (p < 0.001).

APACHE II and IV scores were available for 73% of the patients. They were not significantly different

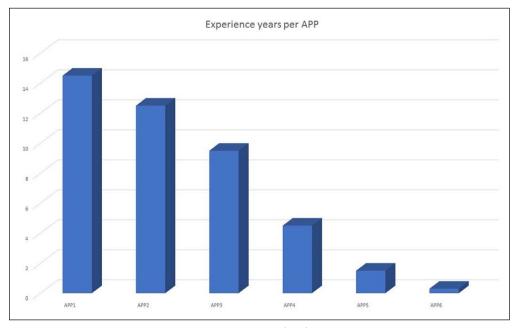


Figure 1. Years of experience of advanced practice provider (APP). Every separate *bar* represents the number of years of experience per APP.

TABLE 1. Baseline Characteristics of Patients and the Performance of Both Groups Regarding
Insertion of Arterial Catheters

Arterial Catheters	Advanced Practice Provider	Medical Resident	р
Total numbers	478	355	
Radial artery, <i>n</i> (%)	317 (66)	265 (74)	0.017
Brachial artery, <i>n</i> (%)	73 (15)	41 (12)	0.14
Femoral artery, n (%)	88 (18)	51 (14)	0.14
Diversion to other sites then radial artery, n (%)	161 (34)	92 (26)	0.048
Systolic blood pressure (mm Hg), median (IQR)	110 (90–125)	110 (90–130)	0.04
Vasopressor use, <i>n</i> (%)	158 (33)	93 (26)	0.035
Ultrasound use, n (%)	53 (11)	60 (17)	0.02
Palpability, n (%)	346 (72)	293 (82)	< 0.001
No. of attempts before success, median (IQR)	1.30 (1.0–1.82)	1.53 (1.0–2.27)	< 0.0001
Success rate at first attempt, n (%)	340 (71)	200 (54)	< 0.0001
Complication rate, n (%)	36 (7.5)	40 (11)	0.09
Acute obstruction arterial vessel, n (%)	0 (0)	1 (< 1)	NA
Hematoma, <i>n</i> (%)	25 (5)	30 (8)	0.91
Bleeding, n (%)	0 (0)	2 (< 1)	NA
Other, <i>n</i> (%)	11 (2)	7 (2)	NA
Need for direct supervision, n (%)	12 (2.5)	77 (22)	< 0.001

IQR = interquartile range, NA = not assessed because of low numbers.

between the APP and MR groups (APACHE II: p = 0.4; APACHE IV: p = 0.92).

APPs were significantly less inclined to use ultrasonography as guidance when inserting arterial catheters (11% vs 17%; p = 0.02). The APPs up till 2 years of experience used ultrasonography as often as the residents. APPs used the radial artery less often than the MRs and diverted to another site more easily (p = 0.017). The complication rate of APPs did not differ from the complication rate of the MRs (7.5% vs 11%; p = 0.09).

One major complication was encountered. After introduction of the guidewire in the femoral artery by one of the MRs, the patient developed an acute arterial occlusion of the lower part of the leg. The other complications as depicted in Table 1 were mostly guide wire advancement problems.

The MRs needed significantly more supervision compared with the APPs (22% vs 2.5%; p < 0.001).

An analysis of the two APPs with less than 2 years of experience showed the same difference. The number of arterial invasive cannulations by this subgroup of APPs was 139, which is 69.5 per FTE (MRs 37 per FTE). The number of attempts before success was significantly less than those of the MRs (median, 1.32; IQR, 1.0–1.83; p < 0.001). Supervision was needed in 8.3% of the cases, less than the 22% of the MRs (p < 0.001).

Central Venous Access

The total number of central venous catheters inserted in the study episode was 436. Four hundred twenty-four were inserted by either

APP or MR as shown in **Table 2**; the remainder was inserted by an APP in training. Two hundred forty-seven procedures were performed by the APPs, and 177 were performed by the MRs. APPs performed 47 central venous catheters per FTE and MRs 19 per FTE.

All venous catheter insertion characteristics are depicted in Table 2. The APPs were significantly more successful regarding the number of attempts before success and the success rate at first attempt. Supervision during catheter insertion was provided to APPs in 15% of the cases and to MRs in 54% of the cases (p < 0.001). The APPs provided significantly more supervision to MRs than MRs provided supervision to colleagues (p < 0.001). A subgroup analysis of the two APPs with less than 2 years of experience showed the same difference. The number of venous catheters inserted by this subgroup of APPs was 57 (28.5 per FTE). The number of attempts before success was significantly less than that of MRs (median, 1.11; IQR, 1.0–1.61; p < 0.002). Supervision was needed in 39% of the cases, which was not significantly different from the MRs.

One hundred sixty-five catheters were placed in the femoral vein by APPs and 110 by MRs. The complications are shown in Table 2. The overall complication rate did not differ between APPs and MRs. One complication was a cardiopulmonary resuscitation due to ventricular tachycardia during insertion of a dialysis catheter in the femoral vein by an MR. The APPs had a significantly higher success rate at their first attempt (p = 0.05).

Thirty catheters were placed in the subclavian vein by APPs and 15 by MRs. Both groups encountered one pneumothorax as major complication.

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TABLE 2. Baseline Characteristics of Patients and the Performance of Both Groups Regarding Insertion of Central Venous Catheters

Central Venous Catheters	Advanced Practice Provider	Medical Resident	p
No. of catheters	247	177	
Femoral vein, <i>n</i> (%)	165 (67)	110 (62)	0.38
Subclavian vein, <i>n</i> (%)	30 (12)	15 (9)	0.30
Jugular vein, <i>n</i> (%)	52 (21)	52 (29)	0.06
Overall			
Ultrasound, <i>n</i> (%)	137 (56)	117 (66)	0.035
No. of attempts before success, median (IQR)	1.20 (1.0-1.71)	1.33 (1.0–1.86)	< 0.005
Success rate at first attempt, n (%)	200 (81)	123 (70)	< 0.005
Total complication rate, n (%)	15 (6)	12 (7)	1.0
Arterial punctures, <i>n</i> (%)	7 (3)	5 (3)	1.0
Major complication rate, <i>n</i> (%)	2(1)	2(1)	NA
Pneumothorax	1	1	NA
Bleeding	0	1	NA
Hematoma	0	3	NA
Arrhythmia + reanimation	0	1	NA
Catheter wrong route	1	0	NA
Other	2	2	NA
Supervision, <i>n</i> (%)	38 (15)	95 (54)	< 0.001
Providing supervision, <i>n</i> (%)	47 (19)	9 (5)	< 0.001
Femoral venous access, n (%)			
No. of catheters	165	110	_
Ultrasound	86 (52)	69 (63)	0.11
Success rate at first attempt	130 (79)	75 (68)	0.05
Arterial punctures	7 (4)	3 (3)	0.74
Major complication rate	0 (0)	1 (1)	_
Subclavian venous access, n (%)			
No. of catheters	30	15	-
Ultrasound	2 (6.7)	3 (6.7)	-
Success rate at first attempt	25 (83)	8 (53)	0.07
Arterial punctures	0 (0)	0 (0)	NA
Major complication rate	1 (3)	1 (7)	NA
Jugular venous access, n (%)			
No. of catheters	52	52	_
Ultrasound	49 (94)	47 (90)	0.71
Success rate at first attempt	45 (87)	40 (77)	0.31
Arterial punctures	1 (2)	2 (4)	NA
Major complication rate	1 (2)	1 (2)	NA

IQR = interquartile range, NA = not assessed because of low numbers.

TABLE 3. Baseline Characteristics of Patients and the Performance of Both Groups Regarding Intubations

Intubations	Advanced Practice Provider	Medical Resident	p
No. of intubations	143	115	_
Video laryngoscope, <i>n</i> (%)	101 (71)	78 (68)	0.73
Direct laryngoscope, <i>n</i> (%)	38 (27)	35 (30)	0.49
Video laryngoscope with gum-elastic bougie, n (%)	4 (3)	2 (2)	NA
Supervision, <i>n</i> (%)	91 (73)	115 (100)	< 0.0001
Provided supervision, <i>n</i> (%)	14 (10)	0 (0)	0.01
Cormack-Lehane $>$ 1, n (%)	44 (31)	33 (30)	0.82
Emergency intubation, <i>n</i> (%)	128 (91)	94 (82)	0.07
Nurse satisfaction teamwork, median (IQR)	4.85 (4.34–5.0)	4.73 (4.22–5.0)	0.02
Complication rate, n (%)	13 (9)	12 (10)	0.88
Complications, <i>n</i> (%)			
Aspiration	1 (< 1)	1 (< 1)	NA
Esophageal intubation	4 (3)	1 (< 1)	NA
Hemodynamic collapse	2 (1)	0 (0)	NA
> 1 attempt	6 (4)	8 (7)	NA
Dislocation of the tube	0	1 (< 1)	NA

IQR = interquartile range, NA = not assessed because of low numbers.

Fifty-two jugular vein catheters were placed by APPs, and 52 jugular vein catheters were placed by MRs. All characteristics of the central venous catheterization are summarized in Table 2. The major complication rate in both groups was equal; the APP encountered one accidentally placed arterial catheter, which could be removed without resulting neurologic impairment. The MRs encountered one hemothorax, which did not require additional intervention.

Intubations

A total of 258 tracheal intubations were performed during the study period. One hundred forty-three (55%) were performed by APPs, and 115 (45%) were performed by MRs (**Table 3**). The APPs performed 27 intubations per FTE during the study period and the MRs 12.

The APPs performed 71% of the intubations with video laryngoscopy and used direct laryngoscopy in 26% of the cases. The MRs used video laryngoscopy in 68% and direct laryngoscopy in 30% of the cases.

The APPs were supervised in 73.4% of the cases and the MRs in 100% of the cases. In 10% of the cases, the supervision to MRs was provided by APPs. No resident was considered experienced enough during this study period to perform intubations without supervision.

The complication rate between MRs and APPs did not differ. The APPs encountered adverse events in 13 cases (9%) and the MRs in 12 (10%) (p = 0.88). Adverse events are shown in Table 3. Multiple attempts to intubate were encountered in 4.2% of the intubations by APPs (6) and in 7.0% by MRs (8).

The APPs scored higher on teamwork (p = 0.02) as judged by the assisting registered nurse. In three cases, the performance of the team with an APP was graded 3 or less, and in one case, the team with an MR was graded 3 or less.

Other Procedures

The other registered procedures are in-hospital transportation, pleural drainage, electrical cardioversion, and changing tracheostomy cannulas. The results are summarized in **Table 4**.

DISCUSSION

We have shown that, in our setting, APPs perform more invasive procedures than MRs during the daily ICU care. According to the

TABLE 4. Characteristics of Other Procedures

	Advanced Practice Provider	Medical Resident	ρ
Pleural drainage			
No. of procedures	10	7	-
Interhospital transport			
No. of procedures	66	54	-
Electrical cardioversion			
No. of procedures	15	14	_
No. of supervised procedures, <i>n</i> (%)	4 (27)	11 (79)	0.059
Changing tracheostomy cannulas			
No. of procedures	4	2	_

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items analyzed during arterial catheterization, the APPs performed these procedures either with comparable success rate or better than MRs. The APPs needed less attempts before a catheter was inserted and needed more often only one attempt. Furthermore, the group of patients treated by APPs used more vasopressors, had lower blood pressure, and the palpation of arteries appeared more difficult. This implies that the APPs treated a more complex group of patients, although the APACHE score between the two groups showed no significant differences. Possibly, experience of the APP plays a role in these differences.

Similar results were found for central venous catheter insertion. The number of catheters introduced by APPs exceeded those of MRs with higher success rates at first attempt. The number of procedures by APPs requiring supervision was less than in the MR group and often the APPs provided supervision to the MRs. Within the group of APPs, we observed no outliers either in poor or excellent performance.

There was an excess in the total number of procedures performed by APPs. Apparently, there is an easy referral of these procedures to APPs by other physicians. This likely occurs because the APP is considered a fast, effective, and safe performer, whereas the MR is often not as experienced as the APP. The term "quality of procedures" is not strictly defined, but in the literature, items like complication rate, number of attempts, time till insertion, overview of the situation, and teamwork are used for the evaluation of procedures. If we use these items as definition for the quality of the procedure, the quality of procedures by APPs was well in the range of established performance rates for clinicians performing these procedures (12, 13). Although in this study, the APPs often refrained from the use of ultrasound, the success rate and complication rate were comparable to the rate mentioned in the literature with the use of ultrasonography (12, 13). These results are remarkable because the studies described in these Cochrane reviews reported data in often less complex patient groups.

A few studies and several abstracts have been published regarding interventions by APPs (5, 14–18). In general, these reports confirm the results of our study. APPs do not have a higher rate of mechanical complications or infections during insertion procedures of central venous catheters (14), neither do APPs have higher complication rates in other procedures (5, 15–17).

Strengths and Limitations

Strengths of this prospective study are the large amount of procedural data which enables a thorough estimation of the performance of APPs, their rates, and some psychological assessment data about team performance and communication.

However, we also acknowledge some limitations. Comparing APPs to residents is comparing a relative experienced group to a group which is still learning interventions. A subgroup analysis of our data with APPs less than 2 years of experience compared with the results in the MR group is probably a more valid comparison. This comparison also shows that in this subgroup, the differences in success rate and the larger amount of procedures remained. This at least justifies the conclusion of noninferiority as far as interventions are concerned. The fact that the complication rate was also low compared with the Cochrane reviews shows that the APP is very capable of performing all kind of procedures safely.

This study is also not randomized and/or blinded. This implies that preferences from either APPs, MRs, or supervisor for certain patients or procedures are not entirely eliminated. Furthermore, the grading of teamwork performance by the nursing staff could potentially be biased. Finally, because no literature has been published about predictions of successful small catheter arterial line insertion, the items we scored could be considered surrogate markers and possibly do not predict quality adequately. Therefore, differences between the groups regarding arterial insertion must be interpreted with caution.

Future Directives

It would be interesting to examine time frames of procedures because they may reflect the ease with which the procedure is performed. Also, more subtle parameters as patient and nurse interaction and evaluation of psychological considerations could attribute to the understanding of the preferential use of either APPs or MRs or intensivists performing procedures.

CONCLUSIONS

This study indicates that APPs are able to perform routine procedures such as arterial catheters, central venous catheters, and tracheal intubations in critically ill patients safe and effectively. Furthermore, APPs perform the procedures more often and more seamlessly. This makes APPs a valuable addition to the professional staff of an ICU.

The authors have disclosed that they do not have any potential conflicts of interest.

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