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Article type : Radiology Original Article

A randomized and controlled study comparing patient controlled and Radiologist controlled intra-procedural conscious sedation, using midazolam and fentanyl, for patients undergoing insertion of a central venous line.

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/1754-9485.12817](https://doi.org/10.1111/1754-9485.12817)

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Key words: sedation, analgesia, central line, interventional radiology.

Abstract

Introduction

Interventional Radiology procedures can provoke anxiety and may be painful. Current practice, Radiologist Controlled Sedation (RCS), involves titrating aliquots of midazolam and fentanyl to patient response but underdosing and overdosing may occur. This study tests a new method of titrating sedation/analgesia during the procedure, Patient Controlled Sedation (PCS), in which a combination of fentanyl and midazolam are administered using a patient-controlled analgesia pump. This allows the patient to self-control their sedation/analgesia during the procedure.

Methods

We performed a randomised control trial comparing the effects of pain, sedation, amnesia, and overall patient satisfaction between PCS and RCS, by enrolling fourty patients undergoing insertion of a tunnelled central line.

Results

Our results showed that PCS was safe, with no adverse events. PCS was effective in providing sedation, amnesia, and overall pain relief comparable to RCS. There was no significant difference in dose given to patients using PCS or RCS. There was a tendency for patients in the PCS group to begin sedation later than those in the RCS group, but both were equally sedated during the procedure. We show that patients in the PCS group were very satisfied with the procedure.

Conclusions

We show that PCS is non-inferior to RCS in terms of dosage given and degree of sedation. To the authors' knowledge, this is the first study to show intra-procedural PCS in an Interventional Radiology setting using midazolam and fentanyl as a randomised comparative trial. It has wide applicability in a procedural setting for very low cost and with minimal additional training required.

Introduction

Diagnostic and therapeutic procedures performed in Interventional Radiology (IR) can provoke anxiety and may be painful [1]. Mild sedation and analgesia is administered by the Interventional Radiologist to calm patient anxiety, reduce unwanted movements and alleviate patient discomfort [1-3].

The most commonly used drug combination for sedation and analgesia is midazolam and fentanyl [1,5]. Midazolam, a benzodiazepine, has a two minute onset and duration of 45-60 minutes. Fentanyl, an opioid, also has a two minute onset and duration of 30-60 minutes [5,6]. Doses are usually administered concurrently with 1 mg midazolam and 25 micrograms fentanyl the usual bolus [1].

Central line placements are commonly performed IR procedures and include Hickman line placement, tunnelled dialysis catheter placement, and injectable port implantation. Intravenous sedation would typically be used for these procedures [4]. This was chosen as a suitable model for the trial based on volume of workload, time of procedure, and reproducibility of procedure between different Radiologists.

Current practice in our institution is that the Interventional Radiologist will assess suitability for sedation, level of anxiety, and expectation of procedural discomfort. Continuous monitoring of heart rate, blood pressure, and oxygen saturation is mandatory and is performed by a dedicated sedation nurse. The radiologist will then decide on the appropriateness of midazolam/fentanyl sedation and choose an initial dose. As the procedure progresses, the level of sedation is assessed and if needed further aliquots of

midazolam/fentanyl are administered at the radiologists' discretion. This is in line with the Royal Australian and New Zealand College of Radiologists (RANZCR) standards of practice, specifically section 3.3 [7]. This practice, Radiologist Controlled Sedation (RCS), is the standard of care around the world in IR and has a very good record of efficacy and safety [1-3]. It has the disadvantage that the Radiologist has only a limited ability to assess the degree of sedation during the procedure by talking to the patient, and is often preoccupied with performing the procedure. It is not uncommon for the patient to ask for further doses of sedation to be given, and this is taken to represent underdosing. There is also potential for overdosing, but this is uncommon [2].

Patient Controlled Sedation (PCS) is a technique that allows the patient to self-administer sedation and analgesia during the procedure by means of computer-controlled IV pump, which is programmable to control the dose delivered, time between doses (lock-out), and total dose limit. This type method is well established in the post-operative setting [1], however there is emerging use of this method during the procedure as an alternative means of providing intra-procedural sedation. In other procedural situations such as dentistry and endoscopy, PCS has been studied and shown to have some advantages [8,9]. With PCS, anxiolysis and pain relief can be achieved with a reduced risk of overdose. It has been shown to enhance patient satisfaction [2].

The aim of the study was to determine the safety and effectiveness of PCS using a tunnelled central line model. It was hypothesised that overall sedation, pain relief, and patient satisfaction will be comparable to the traditional practice of RCS.

Methods

Ethics

Ethics approval was granted from our Institutional Research and Ethics Committee. The study was designed in consultation with a consultant Anaesthetist and our Pharmacy department. The use of midazolam and fentanyl for the purpose of this study were in line with the Therapeutic Goods Administration approved indications of use. A small 10 patient study was conducted to prove safety and concept [10]. The study was funded by a research

grant from the Royal Australian and New Zealand College of Radiologists (grant 2014/RANZCR/009).

Inclusion criteria

Patients referred for insertion of a tunnelled central line (Hickman Central Venous Catheter, Bard USA), tunnelled dialysis catheter (Pallindrome Symmetric Tip Dialysis Catheter, Medtronic, USA), or implanted port (Bard Power Port, Bard USA) performed in IR were recruited. We enrolled both inpatients and outpatients who were able to provide written consent for the study.

Exclusion criteria

Patients that were deemed to require consultant anaesthetist involvement (example but not limited to American Society of Anaesthesiologists (ASA) Physical Status Classification >3, multiple co-morbidities, sleep apnoea) or were deemed suitable for local anaesthetic only (e.g. non-fasted or high risk for sedation), were not enrolled. Specific exclusion criteria for the study included patients outside the age range of 18-75, pregnancy, coagulopathy (INR>2 or platelets <50), allergy to intravenous iodinated contrast/midazolam/fentanyl, ASA >3, therapeutic anticoagulation, sepsis, cellulitis at planned insertion site, on protease inhibitors or antiretroviral drugs, altered conscious state, head injury, significant hepatic dysfunction, head or neck tumours, not fasted for at least 4 hours, and inability to provide informed written consent.

Randomisation

The study was designed in conjunction with a statistician and based on our patient volume and the results of a small pilot study [10]. Forty patients were anticipated, and randomisation was generated by a computer program to allocate patients into one of two groups, either PCS or RCS. The computer randomisation results were placed into sealed, consecutively numbered, dark brown envelopes and stored securely. On the day of procedure, after written consent was obtained, the randomisation group was chosen from one of the sealed envelopes.

Materials

For patients randomised to PCS, a syringe was prepared using a combination of 8 mg Midazolam, 200 micrograms Fentanyl, and 28 ml of 0.9% saline, making a total of 40 ml volume. The syringe was loaded to the standard patient controlled pump available in this hospital and many hospitals across the world; Cardinal IVAC PCAM syringe pump PCA system (Cardinal Health, Switzerland). This pump has a single hand-held button which, when pressed, triggers the release of a single bolus. Each 5 ml bolus in our system (programmed into the pump) contained a combination of 1 mg Midazolam and 25 micrograms Fentanyl which as described is a standard aliquot. The machine was set to the minimum 3 minute period available before the next dose could be given which provided a “dose lockout”. The patient controlled activation button could potentially be removed from the patient if an adverse event occurred.

For patients randomised to RCS, syringes of 8 mg Midazolam, 200 micrograms Fentanyl, and 20 ml 0.9% saline (as flush) were prepared per standard hospital protocol, labelled, and placed next to the patient. These were administered intravenously by the sedation nurse assigned to the case under instruction from the Interventional Radiologist during the procedure.

Endpoint - Efficacy

The primary efficacy endpoints for the study were to assess sedation, pain, patient satisfaction, and amnesia. We deemed success to be achieved if the recorded levels were similar between the PCS and RCS groups. Sedation was assessed using the Victorian Standard Sedation score [12]. Pain was assessed using a 10-point visual analogue scale. Patient satisfaction was assessed using a questionnaire (table 1) [12]. There was no suitable evidence-based tool for amnesia assessment in the literature [11,13], therefore we designed our own assessment tool (table 2).

Endpoint - Safety

The primary safety endpoints for the study were to assess for the presence of any adverse events, side effects, and overdosing [14-15]. We deemed success to be achieved if the recorded levels were similar between the PCS and RCS groups.

Procedure

Procedures were performed either by an accredited consultant Interventional Radiologist or by an advanced trainee under the direct supervision of a consultant Interventional Radiologist.

Each procedure was separated into six main timepoints T1-T6 to assist with comparison between the groups (table 2). At each time point sedation and pain scores were recorded.

At two hours following the procedure, patients were asked to fill out a written questionnaire to indicate overall satisfaction with the procedure (table 1). Any side effects or complications were noted, and whether the patient was suitable for discharge as per local hospital sedation guidelines.

Statistics

Statistical analysis was performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA). Continuous variables were summarised using mean (standard deviation) or median (inter-quartile range) where appropriate. Categorical variables were reported as counts and percentages. Comparisons between RCS vs. PCS were made using the Student t test or Mann-Whitney U test as appropriate for continuous variables and chi-square or Fisher's exact test for categorical variables. All calculated p values were two-tailed with $p < 0.05$ indicating statistical significance.

Non-inferiority statistics were applied, significance level (alpha) was 5%, power 90% and percentage success in each group was deemed high (95% as the procedures were straight forward and uncomplicated), and the non-inferiority limit (d) was 20% giving a calculated sample size of 21 per group.

Results

Forty patients were enrolled into the trial (table 3). There was no significant difference between the groups for age, gender, ASA score, procedure time, patient previous experience with the procedure and type of central line inserted. The average age was 54 in

the total cohort, and also in each of the subgroups. There were 31 males and 9 females enrolled. In the PCS group, there were 17 males and 3 females, while in the RCS group there were 14 males and 6 females. The overall average ASA was 2.3, 2.4 in the PCS group and 2.2 in the RCS group. The average procedure time was 36 minutes in total, 35 in the PCS group, and 38 in the RCS group.

There was no significant difference in the dose of midazolam or fentanyl between the groups. The average dose of midazolam was 2.9 mg in the total cohort. In the PCS group the average dose was 3.2 mg and in the RCS group the average dose was 2.7 mg (table 4), $p = 0.655$.

The average dose of fentanyl was 72 micrograms in the total cohort. In the PCS group the average dose was 79 micrograms and in the RCS group the average was 65 micrograms (table 4), $p = 0.770$.

Table 5 outlines the overall number of successful and unsuccessful button demands during the procedure.

Patients overall had a very low pain score in both groups on the visual analogue scale, averaging <1 out of 10 at all the time points, the medians and interquartile ranges were 0 and there was no significant difference between the groups (table 6).

The overall sedation score followed a typical sedation curve, and was comparable between groups (table 7, figure 1). At the T2 timepoint there was a lower sedation score in the RCS group, $p = 0.047$ but the figures were not significant ($p > 0.05$) at the remaining timepoints (T1, T3, T4, or T5).

All patients had full recall of events at T1, this gradually reduced as the procedure progressed, and was comparable between the groups (table 8, figure 2). The degree of amnesia experienced in the PCS group (figure 3) and the RCS group (figure 4) correlated with the increasing sedation.

All patients showed extremely high satisfaction with the procedure on a 0-10 scaling, and the degree of sedation averaging >9.5 out of 10 on the questionnaire (table 9).

There was a mixed response from patients regarding the perceived importance of being in control of sedation/analgesia, the overall average was 7.4 out of 10, however measured 7.9 out of 10 in the PCS group and 6.9 out of 10 in the RCS group, $p = 0.580$ (table 9).

There were no adverse events out of 20 patients in each group (table 3). All 40 patients were deemed suitable for discharge at 2 hours post-procedure.

Discussion

To the authors' best knowledge, this is the first published use of intra-procedural PCS in Interventional Radiology using the familiar and well-established combination of midazolam and fentanyl.

The procedure was found to be safe with no adverse events, and all patients were able to meet hospital guidelines for discharge at 2 hours post procedure.

Our results show that there is no significant difference (non-inferiority) in the dose given to each patient when comparing PCS and RCS, and no significant difference in the level of sedation during the procedure from the time local anaesthetic is administered.

Looking closer at the level of sedation achieved for each individual timepoint, at T2 (prep and drape) patients in the RCS group were more sedated than in the PCS group. This evened out by T3 (local anaesthetic) where level of sedation was not statistically different. By taking into account time of action of midazolam, the results suggest that patients using PCS have held off sedation during the earlier timepoint when there is minimal stimulus, but began giving themselves sedation when there is the physical stimulus and have caught up to a similar level of sedation by T3 (local anaesthetic). The sedative effect has worked just when needed. Patients were overall well sedated in both groups during catheter tunnelling which may be the most stimulating component.

Amnesia was comparable between the two groups and followed the degree of sedation well. This outcome is often desired by the Interventional Radiologist and the use of PCS did not obviate this effect. It is acknowledged that the tool used to measure amnesia for this study was novel rather than evidence based and that there is a social/cultural bias to some of the questions. However, given an established method was not available we found that this tool was simple to administer and the results aligned with the validated sedation tool used for the study.

Severe pain is usually not anticipated after appropriate administration of local anaesthetic, and both cohorts in this study experienced a low overall pain level. A potential disadvantage with PCS is that because the mixture is already made, fentanyl cannot be given on its own if unexpected pain were to be encountered during the case. The alternative view to this is that if the patient experiences pain, they are able to press the button for a new dose straight away, and this level of control may help modify their subconscious neurological response to the stimulus and positively affect their perception of pain.

It can be difficult for a hospital worker to empathise with the anxious patient who may be potentially new to a hospital environment, and to understand what patients need to control their symptoms, which is subjective in its assessment. The individual physiology and pain tolerance of each patient also means that the response to sedatives/analgesia will be different and individual variations are difficult to predict. Both these scenarios highlight advantages of PCS use as it will tailor the anxiolytic, sedative, and analgesic effect to each individual patients' needs. The overall dose given in each group also shows that the lockout feature can prevent overdosing. Interestingly, there were five patients in the PCS group who pressed the button for sedation only once and this shows that we cannot always predict which patients may not need sedation for a procedure. On these occasions the Interventional Radiologist was surprised with the small dose, and had admitted that they would have predicted a higher dose would be given if they had been under traditional RCS.

Overall patient satisfaction can be challenging to quantify and varies depending on many factors including patient expectations and background anxiety. In this study we enrolled

patients with a varied prior experience of invasive IR procedures, some who have had multiple ports or Hickman catheters, and some experiencing hospital or IR procedures for the first time (e.g. new diagnosis leukaemia, urgent dialysis, new diagnosis cancer about to start chemotherapy – in some instances the same day as port insertion!). This all influences patient experience. All patients informed us that they had a subjectively high level of satisfaction with pain relief, the procedure, and the PCS concept. There were some patients in the PCS group who had experience with RCS previously and there were some who did not. We acknowledge that the study would be more powerful if patients could experience both groups however this would require a different model than for tunnelled central lines of which a repeat procedure is not usually anticipated. In spite of this we were encouraged by the overall positive patient experience and while this not necessarily scientific, is still a goal of medical care.

We propose that there are some patients who may see additional benefit from PCS over RCS. PCS provides the advantage of knowing they will have a dose of sedation/analgesia that they feel appropriate to their needs, and a sense of autonomy at a time when they have little other control over events. However, we also recognise that there are some patients who do not want the additional responsibility of PCS for various reasons, such as being overwhelmed by a new diagnosis of cancer or severe anxiety about upcoming treatment. It is usually very clear during the initial consultation whether a patient will benefit from PCS, and this is a decision for the Radiology team and the patient to make in co-operation.

The setup to provide a PCS service is straightforward, and both drugs fall within many international regulatory guidelines for use. Standard hospital equipment was used, including syringes and pump. There was no additional training required for Radiologist or nursing use of this equipment above that expected from their qualifications. Essentially, this service has the potential to be offered by any angiographic or general procedural service, in almost any hospital, in almost any country, even with limited resources and training. For this reason, we chose to prove this concept with short acting drugs (midazolam/fentanyl) rather than switching to ultra-short acting versions (e.g. remifentanyl/remimazolam) [16,17] which may work better with the intra-procedural PCS concept, but are unfamiliar to Radiologists.

While the overall sample size was small, this model should be easy to apply to a larger sample and could easily be adapted to other Radiology or non-Radiology procedures. We acknowledge that in an effort to reduce complexity in an otherwise new procedure we were not able to offer this as a blinded or sham trial and thus we introduce some bias. Also while the randomisation proved successful, we did not intentionally match the participants.

Conclusion

We show for the first time in an IR setting that the use of patient-controlled intra-procedural sedation is possible using the established and familiar combination of Midazolam and Fentanyl. We show that it is safe and effective, but also results in a high level of patient satisfaction. We show that there is no significant difference between PCS and RCS dose and level of sedation during the procedure itself, i.e. that PCS is non-inferior when compared to RCS.

There is the scope to improve overall patient satisfaction with the use of PCS, by providing control and autonomy for patients. In the appropriate patient setting, this provides another very useful tool for the proceduralist to consider and this can be performed with limited cost and resources. This concept may be applied more widely in Radiology and other procedural environments.

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Tables

Table 1 – Patient questionnaire

	Question (scored numerically from 0 to 10)
1	Overall rating for satisfaction with care
2	Satisfaction with the procedure
3	Satisfaction with overall contact with staff
4	Satisfaction with response of nursing staff to meet needs
5	Satisfaction with pain relief
6	How important do you feel it is to be in control of sedation?

Table 2 – Amnesia test

Timepoint	Trigger	Item asked to remember and recall later	Pain assessed	Sedation assessed
T1	Surgical scrub	Barrack Obama	Yes	Yes
T2	Prep and drape	Paris	Yes	Yes
T3	Local anaesthetic	Fox	Yes	Yes
T4	Tunnel chest wall	Star Wars	Yes	Yes
T5	Dressing applied	St Valentine's Day	Yes	Yes

T6	1 hour after T5.	Recall of the above 5 items to assess level of amnesia.
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Table 3 – Patient characteristics

	PCS (n=20)	RCS (n=20)	p value
Age (years), mean (SD)	54.4 (14.3)	53.3 (13.6)	0.80
Male gender, n (%)	17 (85)	14 (70)	0.45
ASA, median (IQR)	3 (2-3)	2.5 (1-3)	0.52
Procedure time (min), mean (SD)	35 (12.8)	37.5 (14.5)	0.57
Adverse events, n (%)	0 (0)	0 (0)	1.00
Procedures	16 Hickman catheter 3 Portacath 1 Permacath	13 Hickman catheter 6 Portacath 1 Permacath	NA
Patient experience	9 first IR procedure 11 previous IR procedure	10 first IR procedure 10 previous IR procedure	1.00

Table 4 – Mean doses of administered Midazolam and Fentanyl

	Total	PCS	RCS	p-value
Midazolam (mg) mean (SD)	2.9 (1.7)	3.2 (0.47)	2.7 (0.26)	0.770
Fentanyl (µg) mean (SD)	71.9 (42.1)	52.7 (11.8)	65.0 (6.1)	0.655

Table 5 – Overall number of successful and unsuccessful PCS demands for each patient

Patient Number	Successful PCS	Unsuccessful PCS
1	4	4
4	2	3
6	4	3

8	6	8
11	7	10
13	4	1
15	8	10
17	3	0
19	5	5
20	1	0
22	3	1
24	2	0
26	2	0
28	1	1
31	1	0
33	3	0
35	1	0
37	1	0
39	4	8
40	1	0

Table 6 – Pain scores, 0-10 on visual analogue scale, medians and interquartile ranges were 0: p-values T1 –T5.

	PCS VAS score /10	RCS VAS score /10	p-value
T1	0	0	1.00
T2	0	0	0.573
T3	0	0	1.00

T4	0	0	0.938
T5	0	0	0.342

Table 7 – Median and Interquartile range VSS sedation score, range 0-3

	PCS	RCS	p-value
T1	0 (0-0)	0 (0-0)	1.00
T2	0 (0-0.5)	1 (0-1)	0.047
T3	1 (0-1)	1 (0-1)	0.270
T4	1 (1-2)	1.5 (1-2)	0.236
T5	1 (0-1)	1 (0-1)	0.607

Table 8 – Amnesia results

	PCS	RCS	p-value
T1	100%	100%	1.00
T2	70%	85%	0.270
T3	45%	45%	1.00
T4	35%	20%	0.302
T5	35%	20%	0.302

NB: 100% = full recall of events, 0% = no recall of events

Table 9 – Median and interquartile range of patient satisfaction questionnaire responses

	PCS	RCS	p-value
Overall satisfaction with care, median (IQR)	10 (10-10)	10 (10-10)	0.081
Satisfied with the procedure, median (IQR)	10 (10-10)	10 (10-10)	0.298
Satisfied with staff, median (IQR)	10 (10-10)	10 (10-10)	0.655
Satisfied with nursing, median (IQR)	10 (10-10)	10 (10-10)	0.965

Satisfied with pain relief, median (IQR)	10 (10-10)	10 (9.5-10)	0.372
How important is it to be in control of sedation/analgesia, median (IQR)	8 (7-10)	8.5 (4-10)	0.580

NB: patients asked to score on 0-10 scale for each of the above

Table and figure legends

Table 1: Patient questionnaire

Table 2: Amnesia test

Table 3: Patient characteristics

Table 4: Mean doses of administered Midazolam and Fentanyl

Table 5: Overall number of successful and unsuccessful PCS demands for each patient

Table 6: Pain scores, 0-10 on visual analogue scale, medians and interquartile ranges

Table 7: Median and Interquartile range VSS sedation score, range 0-3

Table 8: Amnesia results

Table 9: Median and interquartile range of patient satisfaction questionnaire responses

Figure 1: Median sedation

Figure 2: Amnesia curves, percentage recall (0-100)

Figure 3: Comparing sedation to amnesia in the PCS group

Figure 4: Comparing sedation to amnesia in the RCS group

Figure 5: Comparing pain to the degree of sedation in both groups

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Title:

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Date:

2018-12

Citation:

Clements, W., Sneddon, D., Kavnoudias, H., Joseph, T., Goh, G. S., Koukounaras, J. & Snow, T. (2018). Randomized and controlled study comparing patient controlled and radiologist controlled intra-procedural conscious sedation, using midazolam and fentanyl, for patients undergoing insertion of a central venous line.. J Med Imaging Radiat Oncol, 62 (6), pp.781-788. <https://doi.org/10.1111/1754-9485.12817>.

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