Applying realistic medicine to intrathecal opioid utilisation in Scotland: do we have a standardised approach?

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Abstract

Intrathecal opioids (ITOs) are commonly administered as part of a multimodal anaesthetic strategy for a variety of surgical procedures. The evolution of laparoscopic surgical techniques has seen the popularity of ITOs increase as they are effective, well tolerated and lack the cardiovascular side effects associated with epidural infusions. The risk of delayed respiratory depression remains a concern; therefore, high-quality post-operative monitoring is vital. The evidence regarding the practicalities of ITO administration such as opioid dose, type, side effect prevalence and ideal post-operative care arrangements are sparse. As such, a variety of clinical opinion has been generated. In order to quantify this variation within Scotland, we devised a short telephone questionnaire regarding ITO utilisation. We contacted 16 acute surgical sites. Of these, 14 confirmed regular utilisation of ITOs. Our survey demonstrated significant variability in practice. Both diamorphine and morphine are utilised, but no centre could provide a reason to justify the choice of one over the other. The commonly administered dose range for both agents ranged between 100 and 1100 µg. Most centres employed post-operative monitoring geared towards the detection of delayed respiratory depression but this was not unanimous. Each centre had a variation on what observations nursing staff were expected to complete in the post-operative period. Itch and nausea were not encountered frequently. Two centres experienced at least one episode of delayed respiratory depression which was detected and treated with no patient harm. In the report to the Scottish Government, 'Realistic Medicine', by the Chief Medical Officer, the need to reduce unnecessary variation in practice and outcomes is highlighted. We believe that a national sprint audit would gather sufficient prospective data to further determine whether a correlation exists between side effect profile and ITO utilisation practice. We hope this would help form a consensus and guide a standardised approach.

Keywords

Intrathecal opioids, delayed respiratory depression, realistic medicine, post-operative analgesia, acute pain, practice variation and outcome

Introduction

Intrathecal opioids (ITOs) are commonly administered as part of a multimodal anaesthetic strategy for a variety of surgical procedures as they provide intense post-operative analgesia.¹ This profound analgesia can be particularly helpful when trying to facilitate enhanced rehabilitation after surgery (ERAS).² For this reason and with the evolution of minimally invasive surgical procedures, the popularity of ITOs has increased over recent years.^{3–5} Traditional acute pain strategies such as patient controlled analgesia (PCA)

morphine delivery systems and epidural local anaesthetic infusion have subsequently decreased in favour of ITOs.^{4–7} Traditionally, ITO use was limited to

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orthopaedics, gynaecology and obstetrics. However, more recently the utilisation of ITOs has expanded into most surgical specialties, particularly vascular, urology and general surgery.³

A particular strength of ITO utilisation in general surgical procedures is that effective post-operative pain control can be achieved without the haemodynamic compromise that would be seen with an epidural infusion. This can reduce unnecessary fluid administration in vulnerable patients, making it a popular choice among our surgical colleagues.⁴ However, unlike epidural infusions, there is not the ability to provide 'top-up' doses for inadequate analgesia during the post-operative period.

ITOs are not without risk and are by no means a benign intervention. Administration of ITOs carry the same risk as any other neuraxial regional anaesthetic technique and include bleeding, infection, post-dural puncture headache, failure, transient and permanent nerve damage. As such there is a population of patients in which ITO administration would be contraindicated. ITOs are generally safe and well tolerated but side effects can include nausea, vomiting, pruritis and sedation.⁸ The most concerning side effect is delayed respiratory depression, and there have been numerous case reports, literature reviews and anecdotal experience in which undetected respiratory depression has caused patient harm.⁸ For this reason, it is recommended that a period of monitoring is required in the initial post-operative period in an environment where staff are trained to detect and treat respiratory depression.⁸

Despite the increasing utilisation of ITOs in Scotland, there does not appear to be a national consensus for their use. Anecdotally, different units have a different ITO protocol in terms of ITO dose, type of ITO and post-operative care arrangements. Consensus guidelines do exist and give helpful recommendations on identifying patients at risk, minimising adverse events and for the detection and management of respiratory depression. However, when considering specific areas such as dose selection, opioid type and recommended post-operative observations, the guidelines are vague, which may reflect the limited evidence base.⁸ This study aims to quantify our practice nationally to determine what variation exists and whether we can determine a national consensus.

Methods

A short telephone questionnaire was constructed under the guidance of the Scottish Society of Acute Pain Services (SSAPS). Formal ethics approval for this study was not required as we did not require access to patients or medical records. With the assistance of

SSAPS, we were able to identify a list of acute hospitals that potentially utilise ITOs as part of their acute pain management.

In September 2016, this survey was conducted by two Anaesthesia Specialty Registrars from the West of Scotland School of Anaesthesia under the supervision of SSAPS. No funding was required for this study.

We made telephone contact with the acute pain team of each site and invited them to complete our short telephone survey. In the first instance, we tried to contact the acute pain specialist nurse for each unit with a contingency to contact the acute pain lead anaesthetist when the acute pain nurse was either unavailable or unable to complete the survey. This project focused on acute pain management of surgical specialties and therefore excluded the obstetric population.

Our survey asked the following questions:

- Does your site utilise ITOs?
- What surgical specialties commonly utilise ITOs?
- What type of ITO do you use most regularly?
- What intrathecal dose range is commonly administered?
- Where are patients who have received ITOs nursed post-operatively?
- Do you have any formal post-operative observation/documentation that your nursing staff complete post-operatively following ITO administration?
- In your experience, do you think ITOs form a helpful part of acute pain management?
- Have you specifically had problems with post-operative respiratory depression, itch, nausea or vomiting?
- Do you have any further comments regarding ITO utilisation in your hospital?

The results were gathered and analysed using Microsoft Excel. Due to the nature of the study and low sample size, formal statistical analysis was not performed.

Results

Using contacts from SSAPS, we were able to identify 17 hospitals with an acute pain service who may potentially have experience with ITOs. We successfully made telephone contact with 16 centres in Scotland. Of these, 14 surveys were fully completed by acute pain nurse specialists with the remaining 2 sites being completed by an acute pain consultant anaesthetist. Of the 16 sites that were contacted, 14 sites confirmed that they utilise ITOs.

Table 1. Intrathecal opioid utilisation by speciality (n = 14).

Specialty	Number of centres which utilise ITOs
General	12
Gynaecology	7
Vascular	7
Orthopaedics	12
Urology	4

ITOs: intrathecal opioids.

Table 2. Type of intrathecal opioid utilised by each centre (n = 14).

Type of intrathecal opioid	Number of centres
Diamorphine exclusively	4
Morphine exclusively	7
Both	2
Uncertain	1

Morphine was the most commonly utilised opioid, being used across seven centres with four centres utilising diamorphine. Two centres used both morphine and diamorphine depending on the type of operation and one respondent was uncertain which opioid was used most commonly. There was no explanation as to why one type of opioid was favoured over another but instead the practice seems to have evolved due to protocol, routine observations and drug availability (Tables 1 and 2).

The administered dose variation of both morphine and diamorphine is outlined in Tables 3 and 4, respectively. The IT morphine dose range was between 100 and 1100 µg. The IT diamorphine range was between 100 and 1000 µg.

When asked whether units have any guidelines to help determine what dose or type of opioid is utilised, only two units were able to confirm the use of a departmental protocol. One site did have a fixed protocol which was guided by patient age; patients under 70 years received 200 µg of morphine, while those aged 70 years or over received only 100 µg. Yet, another centre stated that their standard dose for their major urology patients was 800 µg of diamorphine, but this was reduced to 500 µg if the patient was deemed to be 'frail'. One centre stated the use of ITOs was anaesthetist specific.

There was a variety in post-operative care requirements with two units sending patients to HDU exclusively, six units sending patients to any ward and six units sending to a specified ward in which the nurses are trained in post-operative monitoring of ITO patients (Table 5).

In terms of monitoring for post-operative respiratory depression, most units did have some form of

Table 3. Dose variation of intrathecal morphine (n = 10).

Dose variation	Number of centres
Unsure	4
100–200 µg	2
300 µg	1
100–500 µg	1
800 µg	1
400–1100 µg	1

Table 4. Dose variation of intrathecal diamorphine (n = 6).

Dose variation	Number of centres
Unsure	1
100–300 µg	3
100–400 µg	1
800–1000 µg	1

Table 5. Post-operative care provision for ITO patients (n = 14).

Post-operative care provision	Number of centres
HDU only	2
'ITO trained ward'	6
Any ward	5
Any ward (if IT morphine dose < 200 µg)	1

ITO: intrathecal opioid; HDU: High Dependency Unit.

mandatory observations. Four units requested hourly observations for 24 hours, four units requested hourly observations for 12 hours and three units requested 2-hourly observations for 24 hours. There were three units that did not insist on any additional observations above routine observations in the post-operative period. There was no correlation between the type of ITO utilised and the duration or intensity of observation instructed by each site (Table 6).

When asked to consider their experience with the traditional side effects of ITOs, only three units stated nausea/vomiting to be problematic. Three units found itch to be problematic. Most units had never experienced any problems with delayed respiratory depression. Two units experienced a near miss relating to delayed post-operative respiratory depression. In one centre, this prompted the introduction of protocols and formalised post-operative observations. The other centre already had strict protocols in place and the episode of respiratory depression was rapidly detected and treated as a result.

When asked for a general comment about their experience with ITOs, the general perception was very

positive. Five centres commented specifically about a dramatic reduction in the use of PCA morphine and epidural infusions with no compromise in post-operative pain scores. One centre commented on the benefits of haemodynamic stability especially in painful upper gastrointestinal (GI) surgical procedures. One centre experienced a perceived reduction in side effects such as urinary retention, itch and nausea since they have switched from morphine to diamorphine. A major elective orthopaedic centre commented that they do not utilise ITOs at all as risk of urinary retention and nausea is unacceptable to them and their post-operative pain control is adequate without adding ITOs. This is in contrast to other centres, two of which in this survey have commented specifically on their usefulness in orthopaedics (Table 7).

Discussion

This survey does highlight some interesting points. Scotland is a small country with a relatively similar patient demographic population in terms of co-morbidities and surgical requirement. Yet the variation in our practice across sites is significant. This is not necessarily a concern and this variation is most likely to be a reflection on the lack of a solid evidence base.³ Despite a thorough review of the literature, we were unable to find any detailed guidance with regard to dose in terms of pharmacokinetics and pharmacodynamics.^{10–15} There does not appear to be any consistent guidance to determine a targeted dose to balance side effect profile

with efficacy.^{1,8} The existing literature does not appear to take into account the wide range of surgical procedures that ITOs are now utilised for intensely painful operations including upper GI surgery.^{2,4}

Our study is simply a survey, which in essence poses more questions than it answers. Furthermore, the quality of a survey relies heavily on the experience of the person answering the questions. We had no specific measures to validate or standardise this in our study, other than ensuring that our participants were either specialist nurses or anaesthetists with an interest in acute pain. Nevertheless, it is interesting to see quantification of our national practice and to highlight the marked variation on our opinion with regard to what an effective, safe dose of ITO actually is. One explanation for the ITO dose variation between sites may be that there might only be a few sites that perform intensely painful operations, which may skew the results. A future prospective audit should document post-operative pain scores and operation performed to determine whether the ITO dose correlates with a particular type of operation. Furthermore, it would be helpful for future audits to collect data beyond the first 24 hours. Thought should be given to establishing a mechanism for ongoing data collection and analysis to help demonstrate and understand trends over time. The variation that we have seen in this study may not be unique to ITOs. As such, future studies should perhaps include other regional techniques such as epidural infusions.

Frustratingly despite many years of ITO utilisation, we are still left with many questions. What is the optimal dose of ITO? Does diamorphine or morphine have a better side effect profile? Is there a dose-response curve? Should we increase the dose for intensely stimulating operations, and if so, by how much? What is the maximum safest dose and at what point do we cross the line between efficacy and safety? What about chronic pain patients?

What is clear, from several case studies, meta-analysis, consensus guidelines and anecdotal experience, ITOs provide intense analgesia but there are potential risks such as delayed respiratory depression. For this

Table 6. Post-operative observation protocol (n = 14).

Protocol	Number of centres
Hourly RR/SpO2 for 24 hours	4
Two-hourly RR/SpO2 for 24 hours	3
Hourly RR/SpO2 for 12 hours	4
Routine observations only – no protocol	3

Table 7. Free comments on experience of intrathecal opioids (n = 14).

Comment	Number of centres expressing similar view
'Our epidural and PCA morphine rate has fallen dramatically with the increase in ITO use – with no deterioration in pain score'.	5
'Better haemodynamics than epidurals for Whipple's procedures'.	1
'Our urinary retention, nausea and itch side effect profile rate has fallen dramatically since we switched from morphine to diamorphine'.	1
'We do not use intrathecal opioids, we employ the CALEDonian technique and we do not feel the need to add intrathecal opioids'.	1
'Especially helpful for orthopaedics'.	2
'Not convinced about their efficacy in general surgery'.	1

reason, it is vital that centres that utilise ITOs have a robust mechanism to ensure that patients are monitored in the immediate post-operative period. This does not necessarily mean within a critical care environment but should be nursed by staff who are trained in the recognition and management of their complications, especially respiratory depression.

We believe if we harness our existing professional networks to collect ITO outcome data, then we could use this to strengthen the evidence base in this area. We believe that if we employed a collaborative approach to collecting audit data, we will be able to gather enough prospective data to help guide future practice. In our Chief Medical Officers report on Realistic Medicine, an area of government concern is the unnecessary variation in practice and outcome.^{16,17} In order to address this, we propose a national audit of ITO utilisation in Scotland. The SSAPS is a network of healthcare professionals with an interest in acute pain throughout Scotland. We aim to utilise this network to gather a cohort of data collectors for each acute pain site in Scotland. This will allow a short period of coordinated data collection from multiple sites in Scotland with particular attention paid to ITO dose, type, indication, post-operative monitoring and whether this has any correlation with adverse events such as respiratory depression. By conducting a sprint audit such as this, we would hope to provide pain practitioners with more evidence and allow a more standardised and scientific approach.

Conflict of interest

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