Procedural sedation and analgesia (PSA) is a skill commonly required when dealing with patients in the emergency department (ED). Typical procedures performed under PSA in the ED or minor theatre setting are reduction of fractures and common dislocations, incision and drainage of abscesses, laceration repair in children, foreign body removal, and evacuation of retained products of conception (RPOC).

Insufficient analgesia is associated with unwanted physiological and psychological side-effects, including increased sympathetic outflow, peripheral vascular resistance, myocardial oxygen consumption, production of carbon dioxide, hypercoagulability, decreased gastric motility, decreased immune function, and the subsequent development of chronic pain.1-3

Considerable research has proved the safety and efficacy of PSA when administered by emergency physicians in ED units around the world. There are few studies on PSA administration by non-specialists in the public health sector in South Africa.5 Over 80% of the population is serviced by the state-funded public sector hospitals, which are often overcrowded and under-resourced.6

The South African Department of Health7 considers that it is the responsibility of the medical officer (MO) or family physician to care for patients in the ED and administer PSA.7 Our objectives were to study the safety and efficacy of PSA when provided by MOs in a South African peri-urban district hospital, and the influence of fasting status and intoxication on sedation outcome and adverse effect rate.

Methods. A retrospective descriptive study in the Emergency Department (ED) of False Bay Hospital (FBH), situated in the southern suburbs of the Cape Town Metro Health District. The study included all patients who received PSA at FBH between 1 March 2007 and 31 August 2009. Variables recorded included age, gender, physical status as determined by the American Society of Anesthesiologists (ASA status), procedure, fasting and intoxication status, PSA medications, adverse effects, rescue manoeuvres performed, if any, and time to discharge. Analysis was largely descriptive and clinical and demographic data are presented as means (standard deviations), medians, ranges and proportions as appropriate. Success of sedation and incidence of adverse effects are presented as proportions.

Results. Of 166 patients, 140 (84.3%) showed a good level of sedation, 14 (8.4%) were inadequately sedated, 5 (3%) were too deeply sedated but showed no signs of respiratory compromise, and 7 (4.2%) developed respiratory side-effects. Respiratory complications were treated with simple airway manoeuvres; no patient required intubation or experienced respiratory problems after waking up. There was no significant difference in the risk of adverse effects between the fasted and non-fasted groups. Mildly intoxicated patients who received PSA were at a higher risk of adverse effects.

Conclusion. PSA can be administered safely by medical officers. Future research should expand on PSA research in this setting and focus on safety and patient satisfaction.
endotracheal intubation, seizure control or analgesia without an
associated procedure were excluded.

The MO in the ED was responsible for selecting patients deemed
suitable for PSA at a level 1 facility, and for the choice of agents used for
PSA. All health care staff participating in PSA had in-house training in
PSA medication, and standardised guidelines were followed.

Drugs were used at doses suitable for PSA as opposed to anaesthetic
doses. Propofol was mixed into a 1:1 solution with ketamine,
commenced at a dosage of 0.2 mg/kg for each drug and titrated to the
desired effect in 2 ml increments (1 ml of the mixed solution contained
5 mg each of propofol and ketamine). Ketamine, when used alone, was
used at a starting dose of 0.5 mg/kg and slowly titrated in increments of
0.2 mg/kg. Drug choices were up to the attending MO.

All MOs administering PSA had attended ACLS (advanced cardiac
life support), ATLS (advanced trauma life support) and PALS
(paediatric advanced life support) courses.

Patients selected for PSA at False Bay Hospital were generally
‘healthy’, meaning ASA (American Society of Anesthesiologists
classification) status 1 or 2, or stable ASA 3 patients, with no
psychiatric disease. Fasting status and intoxication with alcohol were
evaluated and the decision to proceed with or defer the procedure
was made on a case-to-case basis by the responsible MO. Patients
who attended the ED for procedures other than D&Cs were not
routinely fasted, 10 patients were mildly intoxicated but found
suitable for PSA, and one procedure was deferred because of the
patient's level of intoxication. All the D&Cs patients were fasted.

Inform consent was obtained for the procedure and sedation.
Ethics approval for the study was obtained from the UCT Ethics
Committee.

Each procedural sedation event was recorded on a standardised
anaesthetic record sheet. Recorded variables included age, sex, ASA
status, presenting problem, fasting status, clinical impression of
intoxication, PSA medications and dosages used, adverse effects, rescue
manoeuvres performed, if any, and time to discharge if discharged or
to other disposal of the patient. Patients were monitored throughout
the procedure with continuous pulse oximetry, and heart rate and
blood pressure were measured before and at 2-minute intervals
after commencement of the procedure. Readiness for discharge was
determined in accordance with an Aldrete score of 9/10.

Adverse events were categorised as follows: (i) apnoea – no
respiratory effort for >20 seconds; (ii) desaturation – oxygen (O2)
saturation <93%; (iii) airway manoeuvre required (bag valve
ventilation); (iv) bradycardia – heart rate <50/min; (v) inadequate
sedation ± cancellation of procedure due to failure of PSA; (vi)
vomiting/nausea; and (vii) hallucinations.

Results
Data were entered into an Excel spreadsheet. Data analysis is largely
descriptive and clinical and demographic data are presented as means
(stdandard deviations (SDs)), medians, ranges, and proportions as
appropriate. Success of sedation and incidence of adverse effects are
presented as proportions.

The mean age was 23 years (SD 17.98). The oldest patient was
88 years and the youngest patient 3 months old. Table I sets out the
frequency of other demographic variables.

The intended procedures could be completed in 165 (99.4%) of
166 patients; 9 (54.42%) experienced minor adverse effects, with no
intubation required and no long-term problems as judged by review
of patient records and of mortality and morbidity meetings for the
time span concerned.

Table II contains the breakdown of adverse events for the PSA
patients. There was no statistically significant difference between
complication rates for male and female patients (p>0.05).

There was a statistical difference in age (p=0.0024) between the
patients who experienced complications and those who did not.
Patients who experienced side-effects from their treatment were
older on average, with a median age of 40 years versus a median age of
22 years for those who did not experience side-effects. The youngest
patient who experienced an adverse effect was 19 years old.

The numbers were too low for statistical analysis of the different
medication groups for complications. However, there was a trend
between a higher complication rate with addition of propofol and use
of multiple sedation drugs.

The numbers were too small for statistically significant conclusions
concerning adverse events in fasted versus non-fasted versus
intoxicated patients, but there was a tendency for intoxicated patients
to develop complications, while there was little difference in the
adverse effect rate between fasted and non-fasted patients (Table III).

Of the patients 143 were discharged after their procedure; the
remaining 23 required admission or referral for further treatment.
None of the admissions or referrals was related to PSA. The mean
discharge time was 73 minutes (SD 60.3), with the lowest time to
discharge being 10 minutes and the highest 222 minutes.

Discussion
The South African Department of Health guidelines place the
provision of PSA under the responsibility of level 1 hospitals. This
research was conducted in such a hospital, staffed by MOs, to
determine the outcome of PSA.

The adverse effect rate (complication rate) overall was low and in
keeping with reports from other countries. An unexpected research outcome was detection of a significant
difference in side-effects in relation to age. The median age of the

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<th>Procedure</th>
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<tbody>
<tr>
<td>Incision and drainage</td>
<td>56 (33.5)</td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>31 (18.5)</td>
</tr>
<tr>
<td>Evacuation of RPOC</td>
<td>28 (17.7)</td>
</tr>
<tr>
<td>Laceration repair</td>
<td>24 (14.4)</td>
</tr>
<tr>
<td>Lumbar puncture</td>
<td>8 (4.6)</td>
</tr>
<tr>
<td>Other</td>
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<td>129 (77.7)</td>
</tr>
<tr>
<td>Not fasted &amp; intoxicated</td>
<td>8 (4.8)</td>
</tr>
<tr>
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Table I. Demographic details of the PSA patients

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<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>70 (42.2)</td>
</tr>
<tr>
<td>Female</td>
<td>96 (57.8)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Paediatric patient (&lt;18 yrs)</td>
<td>57 (34)</td>
</tr>
<tr>
<td>ASA status</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>142 (85.6)</td>
</tr>
<tr>
<td>2</td>
<td>11 (6.6)</td>
</tr>
<tr>
<td>3</td>
<td>13 (7.8)</td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
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propofol has a respiratory depressant effect and a combination of multi-drug regimens and addition of propofol. This is expected, as midazolam, ketamine or an opiate) for PSA.

Of a dislocated joint is more difficult, and reduction should therefore always closely followed. While it may be argued that later reduction regarding administration of PSA to intoxicated patients, were not to small patient numbers, it indicates that guidelines, especially in our series. While this finding is not statistically significant owing to low patient numbers, as future use of this medication combination for PSA will be be an interesting topic for future research.

We also suspect that attending MOs may in general be more 'careful' when sedating children, and hesitant to prescribe larger doses or combinations of drugs. We did not examine how far this might have led to under-dosing of the children involved, which might be an interesting topic for future research.

Comparison of the PSA medication that children and adults received showed that while 55 (50.5%) of adults received ketamine and midazolam, 42 (75.4%) of children had single agents (N2O, midazolam, ketamine or an opiate) for PSA.

A trend was found towards a higher risk of complications with combination of alcohol, morphine and midazolam (with the added ketamine) predisposed the patient to adverse effects.

Comparison of the PSA medication used showed that while 49 (98%) of adults received ketamine 1:1 with midazolam ± N2O, 61 (96.8%) of children received ketamine and midazolam ± N2O.

Limitations
While this study was a moderately powered retrospective case review, it lacks the numbers to uncover a serious adverse event. The expected numbers of sedation-induced deaths or permanent neurological injuries are small, in the order of one in tens of thousands. Patient numbers in the order of 50 000 would be needed to investigate these events.

Rating of a 'successful' procedure is a problem, especially from a patient-centred family physician approach. Rates of sedative failure have been reported to be as low as 1 - 3% and as high as 10 - 20% and 20% While the success rate depends on the setting (including the drugs used, the provider, psychological support, and presence or absence of a parent in PSA of children), it also depends on the definition used for successful sedation. In this study PSA was judged to be successful if the procedure could be completed. The condition

### Table II. Adverse events and sedation outcome in relation to PSA medication used

<table>
<thead>
<tr>
<th>PSA medication</th>
<th>Apnoea (O2 saturation &lt;93%)</th>
<th>Desaturation</th>
<th>Hallucination</th>
<th>PONV</th>
<th>No complication/total procedures (%)</th>
<th>Light sedation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketofol (1:1 ketamine + propofol) + midazolam ± N2O</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5/6 (83.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Opiate + midazolam ± ketamine ± N2O</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
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<td>1</td>
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</tr>
<tr>
<td>Single-agent midazolam or ketamine</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>13/13 (100)</td>
<td>4 (2.4)</td>
</tr>
<tr>
<td>Total (N (%))</td>
<td>4 (2.41)</td>
<td>3 (1.81)</td>
<td>1 (0.6)</td>
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<td>157/166 (94.6)</td>
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Chi-square test: p=0.24 (not statistically significant).
PONV = postoperative nausea and vomiting.

### Table III. Adverse events in relation to fasting status and intoxication

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patients who experienced complications was 40 years versus 23 years in those who did not (two-sample Wilcoxon rank-sum test: p=0.0024). There may be two reasons for this. Firstly, advanced age is known to be a risk factor for anaesthetic complications and complications of PSA. Secondly, most paediatric patients received fewer and lower doses of PSA drugs; 22 (38.6%) of all children presented for laceration repair, while the more painful incision and drainage of abscess was the most common procedure in adults (41.3%). Laceration repair requires 'lighter' anxiolytic medication in order for the child to allow infiltration of the affected skin for pain relief. As such, side-effects relating to the use of PSA medication would be less likely.

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of the patient was not described further. This study would therefore have described a procedure done on a child who received PSA but screamed during the procedure and then slept deeply afterwards as a ‘success’ when in reality it was not.

A patient satisfaction questionnaire is probably the only way to ascertain true success of a procedure in a holistic, patient-centred way, and more research on PSA should be planned using this approach.

Some might feel that lack of a standardised drug regimen was a limitation. However, the research question was not to prove superiority of a certain drug for providing PSA, but to prove that PSA can be administered safely by non-specialised but trained medical staff.

**Conclusion**

PSA can be administered safely by MOs in district hospitals. Future research should expand on PSA research in this setting, focusing not just on safety but also on patient satisfaction with PSA.

Newly qualified doctors in South Africa are likely to spend their first few years in district level care. Safe provision of PSA should therefore be taught to more doctors (as a postgraduate course) and even to undergraduate medical students.

Adherence to PSA guidelines, knowledge of drugs and basic airway management are of the utmost importance.

Most importantly, the relief and avoidance of pain is central to our role as humane professionals providing quality health care.

**References**


**Accepted 2 June 2011.**