

# The benefits of reducing anxiety in a Podiatric Surgical Unit in the UK with Midazolam

## *Los beneficios de la reducción de la ansiedad con Midazolam en una Unidad de Cirugía Podológica en el Reino Unido*

**David R. TOLLAFIELD FCPodS, FCPodMED, BSc(HONS), DPodM<sup>\*</sup>,  
Rui DUARTE BSc, PhD, MBPsS<sup>2,3</sup>, Nike AKINWALE FRCA<sup>4</sup>,  
Robert L. ASHFORD PhD, FCPodMED, FFPM RCSP (GLASG)<sup>2</sup>,  
Sian THOMASSON BSc(HONS), MSc<sup>1</sup>**

<sup>1</sup> NB Mr Tollafield is a consultant podiatric surgeon and now works at Spire Little Aston Hospital in the West Midlands with one of his co-authors Dr C Akinwale FRCA who is herself a consultant anaesthetist.

<sup>\*</sup>Corresponding author: david.tollafield@spirehealthcare.com

<sup>2</sup> Faculty of Health, City South Campus, Birmingham City University, B15 3TN, Birmingham, UK.  
ruivduarte@gmail.com; robert.ashford@bcu.ac.uk

<sup>3</sup> Department of Pain Management, Russells Hall Hospital, DY1 2HQ Dudley, UK.

<sup>4</sup> Department of Anaesthetics, Walsall Healthcare NHS, Manor Hospital, Walsall, WS2 9PS, UK.  
Catherine.akinwale@walsallhealthcare.nhs

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### ABSTRACT

Sedation has been frequently used alongside many surgical interventions under local anaesthetics (LA). In podiatric surgery, there is a paucity of literature on the effects of sedation drugs on surrogate measures of patients' physiological signs. General anaesthetic is practised more frequently than sedation assisted local anaesthetic in podiatry. The aim of this audit was to analyse blood pressure (BP) and heart rate (HR) against the administration of midazolam.

A retrospective assessment of sedation notes prior to podiatric procedures undertaken during the years 2008/2009 was performed. BP (systolic/diastolic mm Hg) and heart rate (beats/min) were recorded prior to the administration of midazolam and for the first 30 minutes following administration.

Ninety-four consecutive patients (74 women, 20 men) were admitted for podiatric surgery. Ninety-nine interventions were performed, with five of the subjects undergoing two procedures. The mean age was 59±13.5 years (21-87) and average midazolam administered 2.8±1.3 mg (0.5-8). Average BP prior to midazolam was 148/85 mm Hg and HR 80. At 30 minutes assessment BP was 136/80 and HR 71. BP and HR differences were significantly different at p<0.001 to the reading prior to administration.

The results presented indicate the use of such a drug as an adjunct to LA in a sedation context has favourable results.

**Keywords:** midazolam; sedation; audit; podiatric surgery.

### RESUMEN

La sedación se ha utilizado con frecuencia junto a muchas de las intervenciones quirúrgicas realizadas bajo anestésicos locales (AL). En la cirugía podológica, hay una escasez de literatura sobre los efectos de la sedación ante las señales fisiológicas de los pacientes. La anestesia general se practica con mayor frecuencia que la sedación con anestésico local en podología. El objetivo de esta estudio fue analizar la presión arterial (PA) y frecuencia cardíaca (FC) en contra de la administración de midazolam.

Se realizó una evaluación retrospectiva de los registros de sedación antes de los procedimientos de podología llevadas a cabo durante los años 2008/2009. La PA (sistólica / diastólica mm de Hg) y la FC (latidos / min) se registraron antes de la administración de midazolam y durante los primeros 30 minutos después de la administración.

Noventa y cuatro pacientes (74 mujeres, 20 hombres) fueron ingresados para cirugía podológica. Se realizaron noventa y nueve intervenciones, con cinco de los sujetos sometidos a dos procedimientos. La edad media fue de 59

$\pm 13,5$  años ( 21-87 ) y la dosis media de midazolam administrado fue  $2,8 \pm 1,3$  mg ( 0,5-8 ) . La media de la PA antes de administrar midazolam fue de 148 /85 mmHg y la FC 80. A los 30 minutos la PA era de 136 /80 y la FC 71 . La PA y la FC fueron significativamente diferentes con una  $p < 0,001$  para la lectura antes de la administración.

Los resultados presentados indican el uso de este fármaco junto con el anestésico local en un contexto de sedación tiene resultados favorables.

**Palabras clave:** midazolam; sedación; auditoría; cirugía podológica.

**Sumario:** 1. Introduction. 2. Acceptance of podiatric surgery in England. 3. Methods. 4. Results. 5. Discussion. 6. Conclusion. References.

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## 1. INTRODUCTION

To our knowledge, no publication has covered the subject of sedation using midazolam in podiatric surgery, despite the growth in podiatric surgery in western countries such as the USA, the UK and Australia. Because a good deal of foot surgery is performed as day case in the community, sedation is limited by local regulations. Orthopaedic day surgery admission for foot and ankle surgery equally does not appear to provide supportive evidence for sedation in the UK. In medicine, midazolam as conscious sedation is used in otolaryngology, gastro-endoscopy for day procedures and catheterisation in cardiac cases.

Midazolam is a benzodiazepam providing anxiolysis, sedation and amnesia as its main actions. It is unlike diazepam as it is painless on intravenous injection. It has a short duration of action due to its high lipophilicity, high metabolic clearance and rapid rate of elimination. These properties make midazolam well suited to be administered for sedation purposes whilst undertaking 'day stay' procedures utilising LA, particularly as recovery is faster than diazepam, but it can last significantly longer in the elderly<sup>1</sup>. The closest 'non-medical' field to podiatric surgery in the UK is undoubtedly dentistry. The case for the use of sedation in dentistry and indeed podiatric surgery are well founded. It has been shown to synergistically complement, where appropriate, the use of local anaesthetic in former<sup>2</sup>, and as this paper suggests, procedures carried out by podiatric surgical specialists.

Podiatric surgery is an established specialty in the UK accounting for some 65 operative day surgery centres. During a period 2010-2013 over 41,000 patients were recorded under the care of podiatry within England (Data source PASCUM-10). Taking data at the time of writing (2013) 8% of podiatric procedures were carried out under general anaesthetic and 5% under sedation assisted local anaesthetic.

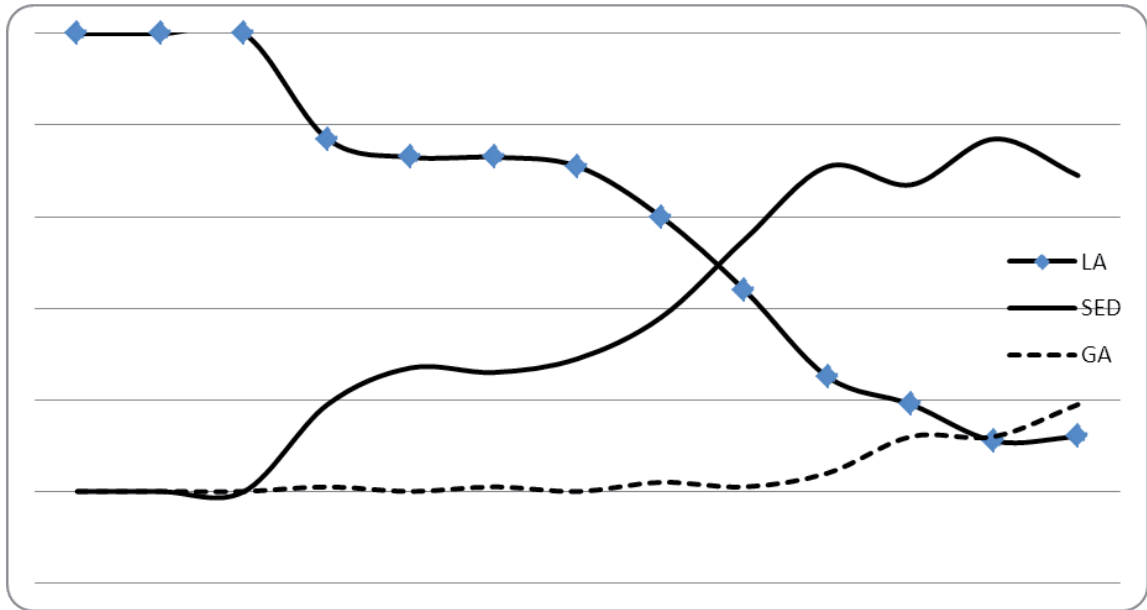
Podiatry (including podiatric surgery) is regulated by the Health and Care Professions Council (HCPC). The sub-specialty of podiatric surgery originally arose from Chiropody<sup>3</sup> but more formally as part of a sub group known as the Podiatry Association in 1974, which initially permitted certain nail surgical procedu-

res to be performed under local anaesthetics. A rapid expansion of the scope of practice developed which eventually included bone and joint surgery within the foot and its associated structures<sup>4</sup>. The work of these early pioneers was performed in small office type theatres in the private sector and it wasn't until 1986 when the first NHS podiatric surgery units were established in Shropshire and Essex that NHS recognition was given to this speciality. Historically, prior to 1974, foot surgery was the sole domain of orthopaedic surgeons in the UK with the majority of the surgery being performed under general anaesthetic, more often with patient overnight admission. With the advent of better amide anaesthetic agents and regional blockades, podiatric specialists were able to expand to more complex foot and ankle procedures.

With the establishment of this new sub-speciality it became necessary to formulate a basic framework in which the scope of practice could operate. As such, the fundamental principles were established which included: securing a safe discharge for all patients; appropriate pain control pre and post-surgery; and reduction of infection risk. Contextually the alignment of this framework also dovetailed into the need to maintain low waiting times and to provide a community based service. NHS funding through a new initiative called GP Fundholding provided a good cost basis for the provision of NHS work. This allowed for better integration of podiatric surgery and so increased volume. By 1998 NHS podiatric surgery had a firm basis with a number of units set up a dedicated theatres in the community, and some serviced integrated services into acute hospital units. Those that worked within the acute hospital setting benefitted from the collaborative services with anaesthetists. By 2003 (Figure 1) general anaesthetic became more frequent and increased to 50% cases. Meanwhile sedation was found helpful in the absence of an attendant anaesthetist with fewer than 10% electing to have local anaesthetic unaided.

## 2. ACCEPTANCE OF PODIATRIC SURGERY IN ENGLAND

Evidence gathered by Tollafield<sup>5</sup> from a selection of general medical practitioners based in a



**Figure 1.** Data for 1993-2005 Walsall Manor Hospital showing growth of sedation (SED) with local anaesthetic (solid line) versus local anaesthetic alone (line with diamond) against growth of general anaesthetic (GA dashed line). The lines cross where sedation was found to benefit patients in three ways; a) commencement of surgery (knife to skin) appeared faster from the time of injection b) the lowering of blood pressure provided a better experience for each patient c) the additional need to top local anaesthetic (LA) up seemed to occur less frequently.

medium sized UK city demonstrated growing support for this fledgling service, which at that point existed exclusively in the private sector.

The current intravenous sedation practice commenced in 1995 and has been modified over time resulting in a practice similar to that recommended by the American Society of Anesthesiology (ASA) guidelines for sedation and analgesia by non-anaesthetists<sup>6,7</sup>. The ASA guidelines are an accepted scale recognised internationally as a system for assessing patient's health in respect to safety for anaesthesia. It is a 1-5 scale where incremental health changes increase the morbidity risk with anaesthetic and surgery. With the expansion of the scope of practice as described above and with the introduction of sedation into podiatric surgical procedures, there is a growing need to be able to document, and indeed demonstrate experience in this area of practice. Therefore the current study utilised a selection of data from the most

widely used database audit system used in the UK: the Podiatric Audit in Surgery and Clinical Outcome measurement PASCOS<sup>8</sup> to illustrate the growth of IV sedation in podiatric surgery for the first 12 years: 1993-2005 (Figure 1). The PASCOS system is well established in the UK and is widely used across many of the UK podiatric surgical units. A corresponding decline in local anaesthetic used as a sole agent can also be seen in Figure 1.

The data reported in this paper utilises cross sectional audit data of sedation between 2008-09. As the only podiatric (surgery) centre in the UK using the technique up until 2013, without an anaesthetist's direct support (anaesthetic sessions are however supported by trained staff in the monitoring of patients), the team sought information that would allow informed reflection on the benefits and effects of midazolam on known measurable parameters routinely used in our theatre.

### 3. METHODS

#### Patients

The sample consisted of 94 consecutive patients, admitted for podiatric surgery between the years 2008 and 2009. During this period 99 interventions were performed; five of the subjects underwent two procedures. Procedures carried out included first ray (osteotomies, implants, arthroplasty, arthrodesis), hammer toes, neuroma surgery; amputations and midfoot fusions. Ankle blocks were utilised in every patient as this technique allows volumes to be delivered to key nerves and ankle tourniquet were used in all cases. Seventy-four of the individuals were women (78.7%) and 20 were men (21.3%). The mean age was  $59 \pm 13.5$  years (range 21 - 87). The average body mass index (BMI) was  $26.8 \pm 3.87$  kg/m<sup>2</sup> (range 20.5 - 34.1).

A medical questionnaire was completed before surgery providing comprehensive information of the patients' present medical and previous surgical and anaesthetic history, along with relevant drug information. Within the initial consultation; standard urine, blood pressure, pulse and body mass index (BMI) were recorded. All patients completed an informed consent. The consent form also highlighted the fact the service offered did not include registered medical practitioners. The method of anaesthetic administration was discussed with each individual patient. This allowed each patient to make an informed decision as to what type of anaesthetic they would prefer. The options offered included local anaesthetic with or without sedation, or general anaesthetic.

A pre-operative assessment was completed prior to the day of surgery in order to act on changes to previous medical history. Pre-operative tests including full blood count, erythrocyte sedimentation rate, urea & electrolytes, liver function test, and 12 lead electrocardiogram (ECG), were performed and reviewed where appropriate. ECG monitoring is mandatory for sedation while blood tests are performed routinely for patients being considered for general anaesthesia but not for local anaesthesia unless medical reasons are recognised.

#### Sedation

An intravenous cannula sited in one of the arm veins was taped securely to prevent movement and dislodgement. Saline 0.5ml was used to flush the cannula ensuring patency and correct positioning. Patients were given midazolam intravenously based on their weight, age and level of anxiety with doses titrated to effect as recommended in the British National Formulary (BNF) section for conscious sedation<sup>1</sup>. The concentration of the drug used was 2mg per ml in a total of 5mls i.e. 10mg per ampoule. An initial dose of 2 mg was infiltrated IV over 1-2 minutes with older or frail and underweight (low BMI) patients getting a lower dose of 0.5 - 1 mg. Additional boluses of 0.5-1 mg were given if desired effect had not been achieved after about 5 minutes. The whole process took about 10 minutes to complete. Weight was used less as a guide rather than the response from slow titration. This method of providing a bolus dose by titration to effect provides a safer approach compared to that done using body weight/mcg, as the total amount of drug used is lower in the former. The outcome of the above was to permit sufficient consciousness to allow the patient be able to talk but feel calm and relaxed.

The process of anxiolysis is also identified with a fall in blood pressure and heart rate. As the procedure is carried out without anaesthetist support no additional drugs are combined.

Blood pressure (BP), heart rate (HR), and oxygen saturation (SO<sub>2</sub>) were measured. SO<sub>2</sub> was maintained at >95-97% with a variable concentration oxygen mask (MCâ) medium concentration receiving oxygen at 4l/min.

#### Exclusion criteria

Patients excluded for surgery mirror those for sedation at our centre. Criteria for exclusion included: obesity; uncontrolled diabetes; high smoking levels and undiagnosed hypertension (based on three repetitive values of which two should be taken at the GP surgery), chronic respiratory disease and renal concerns. Children (under 16 years) were excluded while patients unfit for surgery were referred for further medical consultation.

### Data collection

A retrospective assessment of sedation notes prior to podiatric surgeries undertaken during the years 2008 and 2009 was performed. Demographical data included age, gender and BMI. Blood pressure (systolic/diastolic mm Hg), heart rate (beats/min) and oxygen saturation (%) were recorded prior to sedation and every five minutes following administration of midazolam. Sedation was evaluated in five minute intervals according to the Ramsay sedation scale. This is a universally accepted tool used to assess levels of sedation in the healthcare setting. First used by Ramsey and colleagues in 1974 it comprises 6 different levels depending on how rousable the patient is<sup>9</sup>.

The data was collected as part of a retrospective clinical audit and therefore ethical approval was not required according to institutional guidelines and the National Research Ethics Service<sup>10</sup>. No additional procedures were carried out for research purposes. No personal medical information or identifiable information is presented within the manuscript. Informed consent prior to administration of midazolam was obtained for all the patients.

### Data analysis

Some of the data did not follow normal distribution and attempts to transform the data were not successful. As analysis of variance is robust to violations of normality, repeated-measures ANOVA were performed to investigate changes in blood pressure, heart rate and sedation throughout 30 minutes following administration of midazolam. Assumption of sphericity was verified through Mauchly's test. If the assumption of sphericity was violated, the degrees of freedom associated with the analysis was to be corrected. Degrees of freedom were corrected using Greenhouse-Geisser estimate of sphericity, when the variances of the differences between levels were significantly different. Changes in blood pressure, heart rate and sedation were controlled for gender, age, BMI and midazolam dose administered.

To further investigate differences between the time points, a Bonferroni correction was applied to not inflate type I error probability; significance represented  $p < 0.008$ . Post hoc tests were conducted using bootstrapped paired-sample  $t$  test based on 10,000 samples.

Data is reported as mean  $\pm$  standard deviation (range). Statistical significance was judged at 5% level except where otherwise mentioned. Statistical tests were performed using the Predictive Analytics SoftWare (version 18.0, SPSS Inc., Chicago, IL, USA).

## 4. RESULTS

The average dose of midazolam administered was  $2.81 \pm 1.28$  mg (range 0.5 – 8). Throughout the period of time evaluated, oxygen levels ranged from 92% to 100%. Assumption of sphericity were violated ( $p < 0.001$ ), therefore the degrees of freedom and the  $p$ -values presented correspond to Greenhouse-Geisser correction. Significant differences prior to administration of midazolam and at intervals of 5 minutes up to 30 minutes were observed for blood pressure and heart rate, but not for sedation according to the Ramsay scale (Table 1). Following a slight increase in sedation between 5 to 10 minutes ( $t(77) = -2.65, p = 0.01$ ), sedation levels remained constant throughout the time periods.

An initial reduction can be observed for both systolic and diastolic blood pressure (Figure 2) followed by apparent stability, while initial heart rate rose slightly followed by a reduction and apparent stabilization (Figure 3).

To further investigate these results, analyses of the different periods were carried out, with significance representing  $p < 0.008$  after a Bonferroni correction (Table 2).

Statistically significant differences were observed for systolic blood pressure prior to and after 5 minutes and for the interval of 5 to 10 minutes, while for diastolic blood pressure and heart rate, statistically significant differences were observed at the 5 to 10 minutes interval. Following this time point, significant differences were not observed in the subsequent intervals for both blood pressure and heart rate, indicating stability.

Gender did not significantly influenced blood pressure ( $p = 0.47 / p = 0.35$ ) or heart rate ( $p = 0.37$ ). Patients' age did not seem to be a contributor to decrease in BP ( $p = 0.47 / p = 0.27$ ) or HR ( $p = 0.96$ ). Systolic ( $p = 0.52$ ) and diastolic ( $p = 0.42$ ) BP, and HR ( $p = 0.71$ ) were not significantly influenced by BMI.

	Blood pressure (systolic/diastolic mm Hg)	Heart rate (beats/min)	Sedation
Before	148.8 ± 19.7 / 85.5 ± 10.1	79.7 ± 15.0	-
5 Minutes	140.7 ± 19.4 / 82.8 ± 10.6	79.9 ± 14.4	1.79 ± 0.6
10 minutes	134.7 ± 16.1 / 78.9 ± 11.2	76.1 ± 13.4	1.95 ± 0.7
15 minutes	133.3 ± 14.1 / 79.4 ± 10.1	74.9 ± 13.8	1.95 ± 0.6
20 minutes	132.9 ± 16.9 / 78.3 ± 11.2	74.3 ± 12.9	1.93 ± 0.7
25 minutes	135.7 ± 15.2 / 80.0 ± 9.7	73.6 ± 12.9	1.92 ± 0.7
30 minutes	135.4 ± 16.5 / 78.6 ± 10.4	72.9 ± 12.1	1.90 ± 0.7
Test statistic	$F(3.87, 247.8) = 12.2 / F(4.83, 304.1) = 6.8$	$F(3.03, 118.2) = 7.57$	$F(3.23, 228.8) = 1.84$
P	<0.001 / <0.001	<0.001	0.135

Mean ± standard deviation

Table 1. Changes in blood pressure, heart rate and sedation.

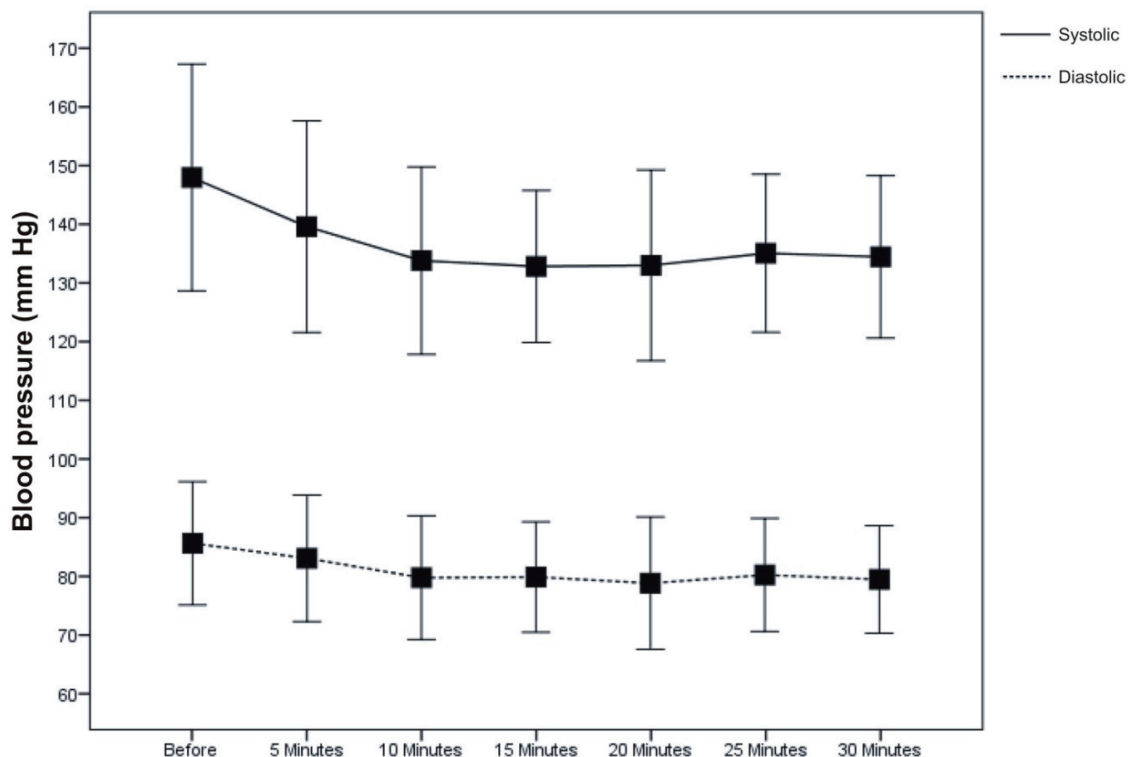
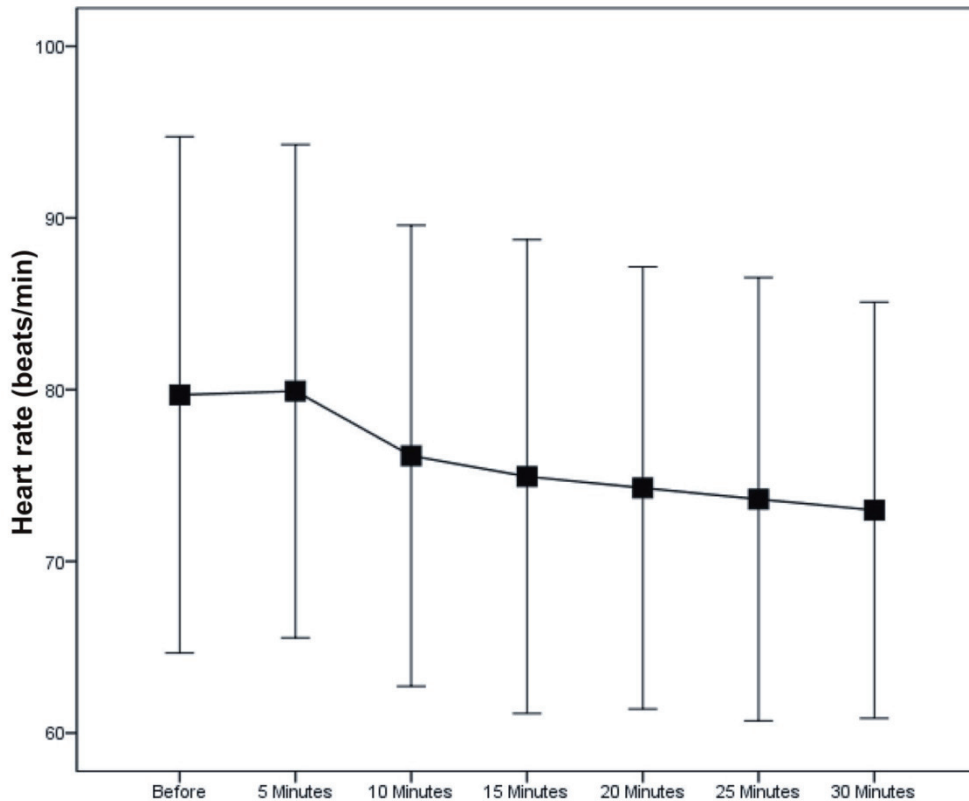


Figure 2. Mean blood pressure following administration of midazolam. Error bars represent standard deviation.

Midazolam dose significantly contributed to a decrease in systolic BP,  $F(42.6, 247.8) = 1.514, p < 0.05$  and diastolic BP,  $F(53.1, 304.1) = 1.708, p < 0.005$ . Midazolam dose contribution to decrease in HR did not reach statistical

significance ( $p = 0.154$ ). Since there were no significant differences in sedation according to the Ramsay scale, this variable was not controlled for the variables gender, age, BMI and midazolam dose.



**Figure 3.** Mean heart rate following administration of midazolam. Error bars represent standard deviation.

	Blood pressure (systolic/diastolic)	Heart rate
Before - 5 Min	$t(88) = 4.19, p < 0.001 / t(88) = 2.46, p = 0.01$	$t(56) = 1.55, p = 0.13$
5 Min - 10 Min	$t(92) = 4.23, p < 0.001 / t(92) = 3.45, p = 0.001$	$t(89) = 5.69, p < 0.001$
10 Min - 15 Min	$t(92) = 0.51, p = 0.61 / t(92) = -0.95, p = 0.35$	$t(93) = 1.22, p = 0.22$
15 min - 20 Min	$t(92) = 0.32, p = 0.76 / t(92) = 1.38, p = 0.18$	$t(93) = 2.32, p = 0.02$
20 Min - 25 Min	$t(92) = -1.91, p = 0.07 / t(92) = -1.83, p = 0.08$	$t(93) = -0.35, p = 0.73$
25 Min - 30 Min	$t(90) = 0.48, p = 0.63 / t(90) = 1.55, p = 0.13$	$t(92) = 1.26, p = 0.21$

A Bonferroni correction indicates  $p < 0.008$  as significant

**Table 2.** Five minute interval differences for blood pressure and heart rate.



## 5. DISCUSSION

To our knowledge, there is no literature on the isolated effect on patient BP and HR with regional ankle blockades with midazolam in podiatric surgery. The technique of regional ankle blockades remains favoured by podiatric surgeons. Midazolam is short lived and works best over the first 30 minutes. We collected physiological data as part of our routine record blood pressure and heart rate, as well as  $SO_2$  to enable us to create a database record of evidence pertaining to patients from 2008-09. In 94 cases, patients responded well to reduction in HR and BP.  $SO_2$  was well controlled at all times and the review of this cohort did not require any medical intervention, peri-operative admission or reversal agent. All patients were older than 20 and none older than 87. Females were seen more frequently for podiatric surgery than males. This can be attributed to a greater awareness of foot pathology and a desire for earlier intervention, often co-associated with higher footwear expectations demanded by society.

In a number of patients who consented for surgery, no self-perceived anxiety was considered and yet evidence showed that blood pressure was elevated from the clinical values. After midazolam had been used the blood pressure reduced. The general view held by the medical profession today is that blood pressure is over treated and that we must be cautious over the phenomenon of "white coat syndrome" which commonly arises when upon admission to hospital or attending a new clinical specialty. Many patients are at risk from being sent home when presenting for day surgery admission due to the misconception that hypertension exists. The use of midazolam provides some support that normal expectations of anxiety can exclude essential hypertension. In the full cohort of patients treated between 1995-2005 only two such cases were sent home where blood pressure did not respond to IV anxiolysis.

While heart rate is an important indicator of release of catecholamines associated with anxiety and pain, midazolam was found in this study to transiently increase heart rate before reducing it. This effect is similar to findings from previous studies [11, 12, 13], and could be partly attributed to decrease in systemic vaso-

lar resistance caused by midazolam. The reduction in catecholamines resulting from anxiolysis leads ultimately to reduction of heart rate and blood pressure. The exact change upon local anaesthesia effectiveness cannot be shown in this audit and would be better afforded by randomised controlled study.

A patient with raised heart rate and blood pressure will respond to midazolam but even with good quality anaesthesia the clinician and sedationist must be aware that a small percentage of patients respond poorly and state that they can feel pain. If after 10 minutes, following an additional titre of midazolam up to 5mg with additional anaesthetic the patient is still both anxious or feels pain, a 'ten minute rule' is applied. It is more often pointless to continue. The patient will need to be scheduled for assisted anaesthetic – general anaesthetic. Nerve stimulated blocks can work but are not used routinely for the ankle at our centre as they are rarely needed.

The results from this study however suggest that while our method is safe and potentially cost effective in comparison to LA, it does not preclude or infer that working with an anaesthetist is not preferred. The reason for such a statement arises to avoid cancellation of cases where it is known that a small number may have to be converted to full general anaesthetic. The authors' are not suggesting that sedation is a substitute for general anaesthesia, and highlight the increasing trend in the use of general anaesthetics in many hospital based podiatric surgical practices. This of course is more closely aligned to orthopaedic hospital practice.

## 6. CONCLUSION

This study allows a more critical review of the effects of midazolam further emphasizing its potential value in podiatry surgery. We have demonstrated that sedation within controlled and well supported environments can afford safe use of an intravenous drug by trained staff. From experience, time to surgical incision appears faster with the use of anxiolysis than without. The importance of this feature seems more relevant where theatre pathway design involves local anaesthetic administration only in

the dedicated anaesthetic room. This contrasts with the method of administering local anaesthetic blocks on a ward without cannulation, monitoring or drug assisted anxiolysis. In the latter case blocks administered one hour before

surgery commences are commonly practised by podiatric surgical services. The use of Midazolam in a podiatric surgical context has utility and does offer an additional adjunct in this every expanding sub-speciality.

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