Nerve stimulator guided pudendal nerve block *versus* general anesthesia for hemorrhoidectomy

[Le bloc du nerf honteux guidé par un neurostimulateur versus l'anesthésie générale pour une hémorroïdectomie]

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Purpose: A randomized clinical trial was undertaken to test the hypothesis that patients receiving a nerve stimulator guided pudendal nerve block for hemorrhoidectomy would experience more effective and prolonged postoperative analgesia and shorter hospital stay compared to patients receiving general anesthesia.

Methods: This was a prospective randomized observer-blinded study. Following Ethics Committee approval and informed consent, 80 patients scheduled for hemorrhoidectomy were randomized to two groups of 40 patients each: general anesthesia alone, or nerve stimulator guided pudendal nerve block. Postoperative pain, the primary outcome variable of the study, was assessed by visual analogue scale scores at pre-determined intervals during the postoperative period. Analgesic consumption, time to return to normal activities, patients' and surgeons' satisfaction, and duration of hospital stay were recorded.

Results: The guided pudendal nerve block group failed in three patients, requiring their conversion to general anesthesia. Otherwise, patients in the pudendal nerve block group experienced better postoperative pain relief at rest ($P < 0.0001$), on walking, sitting, and defecation ($P < 0.001$), reduced need for opioids (11/35 *vs* 32/37; $P < 0.0001$), a more rapid return to normal activities (7.2 *vs* 13.8 days; $P < 0.0001$) and also a shorter hospital stay (25/35 *vs* 3/37 outpatient cases; $P < 0.0001$) compared to the general anesthesia group. Pudendal nerve block was also associated with overall higher patient satisfaction compared to general anesthesia (30/35 *vs* 9/37; $P < 0.0001$).

Conclusion: Nerve stimulator guided pudendal nerve block is associated with reduced postoperative pain, shortened hospital stay, and earlier return to normal activity compared to general anesthesia for hemorrhoidectomy.

***Objectif** : Tester l'hypothèse voulant que les patients qui reçoivent un bloc du nerf honteux guidé par neurostimulation pour une hémorroïdectomie vont connaître une analgésie postopératoire plus efficace et prolongée et un plus court séjour hospitalier que ceux qui reçoivent une anesthésie générale.*

***Méthode** : Nous avons réalisé une étude prospective, randomisée et à l'insu de l'observateur. Avec l'approbation du Comité d'éthique et le consentement éclairé des participants, 80 patients devant subir une hémorroïdectomie ont été répartis en deux groupes de 40 et ont reçu une anesthésie générale ou un bloc du nerf honteux guidé par neurostimulation. La douleur postopératoire a été évaluée par les scores à l'échelle visuelle analogique à des intervalles de temps prédéterminés après l'opération. La consommation d'analgésique, le temps nécessaire au retour à des activités normales, la satisfaction du patient et du chirurgien et la durée du séjour hospitalier ont été notés.*

***Résultats** : Le bloc du nerf honteux a échoué chez trois patients qui ont dû recevoir une anesthésie générale. Autrement, les patients qui ont reçu le bloc ont connu un meilleur soulagement de la douleur postopératoire au repos ($P < 0,0001$), lors de la marche, en position assise et à la défécation ($P < 0,01$), des besoins réduits d'opioïdes (11/35 vs 32/37 ; $P < 0,0001$), un retour plus rapide aux activités normales (7,2 vs 13,8 jours ; $P < 0,0001$) et aussi un séjour hospitalier plus court (25/35 vs 3/37 cas ambulatoires ; $P < 0,0001$) comparés à ceux qui ont reçu une anesthésie générale. Le bloc du nerf honteux a été aussi associé à une plus grande satisfaction globale (30/35 vs 9/37 ; $P< 0,0001$).*

***Conclusion** : Le bloc du nerf honteux guidé par neurostimulation comparé à l'anesthésie générale pour une hémorroïdectomie est associé à une réduction de la douleur postopératoire, à un plus court séjour hospitalier et à un retour précoce aux activités normales.*

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REGIONAL anesthesia has been used as an alternative to general anesthesia (GA) for hemorrhoid surgery in order to reduce the incidence and severity of postoperative pain, while reducing the duration of hospital stay.[1–7] However, the benefit of regional anesthesia without catheter techniques limits their duration of action to the immediate postoperative period. Thus, a more extended period of postoperative analgesia would represent a much welcomed clinical improvement.

In a recent randomized double-blind study we showed that nerve-stimulator guided pudendal nerve block (PNB) combined with GA reduces postoperative pain, and results in a shorter hospital stay and earlier return to normal activity compared to GA alone.[8] Based on the positive results achieved with this type of PNB, we hypothesized that it would be possible to perform hemorrhoidectomy without concomitant GA. Thus, we undertook a prospective randomized observer-blinded study to compare nerve-stimulator guided PNB with sedation, to GA in patients undergoing hemorrhoidectomy. We hypothesized that patients treated with PNB would experience better and more prolonged postoperative analgesia.

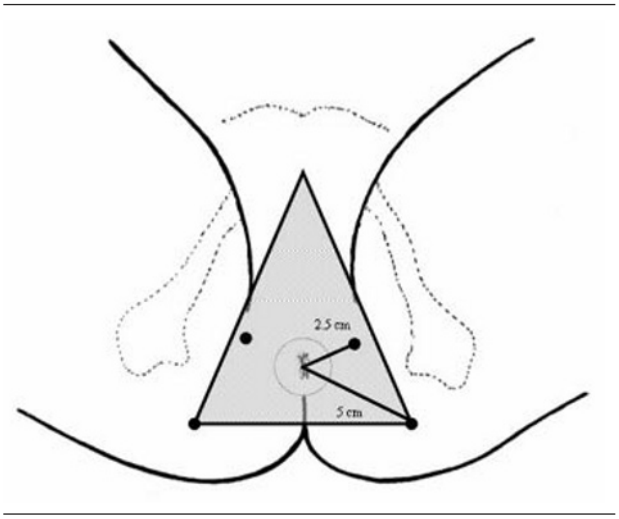

FIGURE 1 Landmarks for the injection points for the pudendal nerve blockade. The site of injection from the anal verge is located about 2.5 cm for the anterior injection points and about 5 cm for the posterior injection points. Δ = the covered anesthetized area with the summit in the perineal area and the base joining the two posterior points.

Methods

Following Ethics Committee approval and after obtaining written informed consent from each subject, 80 patients aged between 20 and 69, scheduled for hemorrhoidectomy with Shackelford's classification grades II–IV[9] were randomized using a computer-generated numbers table. Patients were allocated, according to the randomization sequence, to one of two groups; GA (GA, n = 40) or bilateral PNB (PNB, n = 40), with or without sedation based upon patient request.

Patients with chronic renal failure, coagulopathy, symptoms of bladder neck obstruction, or patients for whom it would not be possible to conduct a telephone follow-up were not eligible for study inclusion. All patients underwent open radical hemorrhoidectomy. Skin flaps were raised next to the squamocutenous junction to reduce the risk for postoperative stricture. Flaps were raised up to the dentate line (origin of the plexus). The plexus was excised and the rectal mucosa was sutured to the fibres of the internal sphincter muscle.

Induction of anesthesia for patients in the GA group was achieved with fentanyl 1.5 $\mu g \cdot kg^{-1}$ *iv* and propofol 1 to 2 $mg \cdot kg^{-1}$ *iv*, followed by endotracheal intubation facilitated with atracurium 0.5 $mg \cdot kg^{-1}$ *iv*. Anesthesia was maintained using sevoflurane 1–3% end-tidal concentration, nitrous oxide 70% and oxygen 30%. The sevoflurane concentration was adjusted as required to maintain heart rate and blood pressure within ± 25% of pre-induction levels.

In the PNB group, blocks were performed with the patient in the lithotomy position. Patients received supplemental oxygen by facemask and fentanyl 1 $\mu g \cdot kg^{-1}$ *iv* was administered following application of routine anesthetic monitors. Upon request, sedation was enhanced prior to the block using midazolam 1 - 2 mg *iv*. After aseptic preparation of the skin, four injection sites were infiltrated, each with 1% lidocaine 1 mL. At the posterior injection points at four and eight o'clock (Figure 1) a 22-G 10 cm nerve stimulator needle (Stimuplex, B.Braun, Melsungen, Germany) was subsequently advanced approximately 7 to 10 cm (depending on patient size) perpendicularly to the skin in all planes, using a stimulating current of 2.5 to 5.0 mA at 1 Hz (Stimuplex, B.Braun, Melsungen, Germany). When appropriate nerve stimulation of the pudendal nerve with its inferior rectal nerve and perineal branches could be verified (visualized as ipsilateral contractions of the posterior parts of the anal sphincter), the needle-tip position was optimized in a normal fashion by preserving muscle contractions while reducing the stimulating current to 0.5–0.6 mA, and the injection was performed.

A similar procedure was used for the anterior injection points (two and ten o'clock) where the needle was only advanced to a depth of 4 to 5 cm. The

response to pudendal nerve stimulation at these locations was contraction of the more anterior parts of the ipsilateral anal sphincter, and also contraction of the transversalis perineum superficial muscle.

A local anesthetic volume of 0.2 $mL \cdot kg^{-1}$ was injected at each of the posterior injection points (four and eight o'clock) and 0.15 $mL \cdot kg^{-1}$ was injected at each of the anterior injection points (2 and 10 o'clock) for a total injection volume of 0.7 $mL \cdot kg^{-1}$. Each 20 mL of the local anesthetic mixture contained: 2% lidocaine 6 mL, lidocaine 2% 6 mL with adrenaline 5 $\mu g \cdot mL^{-1}$, 0.5% bupivacaine 5 mL, fentanyl 50 µg, and clonidine 150 µg. This mixture has previously been reported to provide long-lasting postoperative analgesia after peripheral nerve blocks performed for various types of surgical interventions.[8,10–13] Verification of adequate distribution of cutaneous anesthesia was determined by a pinprick test. The onset time of the block was usually 15 to 20 min. Intraoperatively, if the patient requested additional sedation due to discomfort or pain, propofol supplementation was provided in 10 to 20 mg *iv* increments (maximum dose 50 mg). The additional sedation was titrated so that verbal contact was always maintained with the patient. In the event of overt block failure, as indicated by insufficient sphincter relaxation or unacceptable patient discomfort, the technique was abandoned and conversion to GA took place, according to the technique described above.

Postoperative pain management protocol

Patients with a visual analogue scale (VAS) > 4 during their hospital stay received pethidine 1 $mg \cdot kg^{-1}$ *im* as supplemental analgesia, whereas patients with a VAS score < 4 received a combination of dextropropoxifen 30 mg *po* and paracetamol 400 mg *po*. Following discharge, patients were prescribed lactulose 20 mL *po* bid and diclonefac sodium 50 mg *po* tid for three weeks. Patients were also prescribed an oral dextropropoxifen/paracetamol combination if they required additional analgesia following hospital discharge.

Data collection

Postoperative data collection was peformed by a trained research nurse who was blinded to patient group allocation. Postoperative VAS pain scores were considered the primary outcome variable of the study. The VAS scores (0- no pain and 100- worst possible pain) at rest, on walking, and sitting were assessed at predetermined intervals postoperatively (6 hr, 12 hr, 24 hr, 36 hr, 48 hr, 3 days, 4 days, 5 days, and 6 days). Pain associated with the first six episodes of defecation, and opioid consumption for the first six postoperative days were also recorded. Following hospital discharge, patients were instructed to record the following: number of postoperative days required to be able to sit, to walk, and to defecate without pain. The times (in days) until return to work (employed patients) or to resume normal activities of daily living (unemployed patients) were also recorded.

Demographic data, duration of surgery, duration of recovery room stay, patient satisfaction, postoperative nausea and vomiting, duration of hospital stay, duration of sick leave time, and complications were recorded. Non-invasive measures of mean arterial pressure, heart rate and oxygen saturation were recorded pre- and postincision. In Group PNB sphincter relaxation was also assessed by the surgeon. If complete sphincter relaxation was not obtained following administration of the block and supplemental sedation, the block was considered to have failed, and the patient was converted to GA.

The decision to discharge the patient from hospital was made by the surgeon according to established clinical routine (discharge criteria: adequate control of pain and postoperative nausea and vomiting, ambulation without aid, and ability to void spontaneously). The patient's overall level of satisfaction was assessed by telephone interview one month postoperatively. Patients were asked to quantify their degree of satisfaction as satisfied, moderately satisfied, or unsatisfied. Patients were also asked whether they would choose the same type of anesthesia if they required a repeat procedure, and if they would recommend the same anesthetic to a sibling or friend who required the same type of surgery.

Statistical considerations

Based upon standard deviations in VAS scores from our previous study,[8] 40 patients in each group were required in order to detect a 25% difference in VAS scores at all predetermined time intervals of the postoperative period between groups, with a confidence level of 95% ($\alpha = 0.05$) and a power of 90% (ß = 0.10).

Student's *t* tests were used to test for differences between groups with respect to age, height, weight, body mass index, recovery room length of stay, time to resume normal activities, and number of days with pain on walking, sitting and at defecation. Chi-squared tests were used to test for differences in postoperative nausea and vomiting, urinary retention and incontinence, readmission due to severe pain, duration of hospital stay, postoperative patient satisfaction, and need for supplemental analgesics. Repeated measures ANOVA was used for between-groups comparison of hemodynamic parameters and VAS pain scores at rest,

TABLE 1 Demographic and intraoperative parameters

	GA (n = 40)	*PNB (n = 40)*	*P-value*
Sex (M/F)	22/18	26/14	NS
Age (yr)	38.0 ± 11.6	36.3 ± 9.3	NS
Height (cm)	165.7 ± 9.5	169.1 ± 8.6	NS
Weight (kg)	71.1 ± 13.2	72.2 ± 13.7	NS
Body mass index ($kg \cdot m^{-2}$)			
< 25/25-30/ > 30 (*n*)	17/19/4	21/16/3	NS
Hemorrhoid grade (I/II/III)	10/16/14	7/15/18	
Employment (yes/no)	8/32	7/33	NS
Duration of surgery (min)	61 ± 15	63 ± 18	NS
Sedation (*n*/%)			
None	NA	17 (42.5%)	
Midazolam	NA	16 (40%)	NA
Midazolam + propofol	NA	4 (10%)	
Conversion to GA	NA	3 (7.5%)	
Sphincter relaxation (n/%)			
Complete/partial	NA	34/6 (85%/15%)	NA
PACU duration (min)	74 ± 27	46 ± 18	0.0001

GA = general anesthesia; PNB = pudendal nerve block; NA = not applicable; NS = not significant. PACU = post-anesthesia care unit.
* Values are mean ± SD unless otherwise specified.

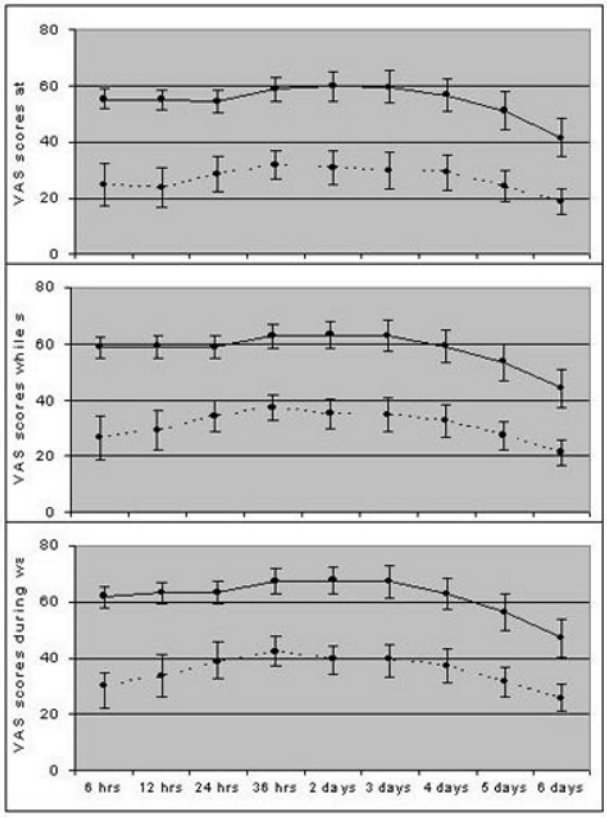

FIGURE 2 Visual analogue scale (VAS) pain scores (mean with corresponding 95% confidence intervals) during the first six postoperative days after hemorrhoidectomy. A significant difference exists for VAS scores at rest, sitting and walking at all time points comparing pudendal nerve block (PNB) and general anesthesia (GA) groups with ($P < 0.0001$). Dotted line = pudendal nerve blockade, straight line = general anesthesia.

on sitting, and on walking. Statistical significance was assumed with a *P*-value < 0.05.

Results

All patients were included in the analysis of pre- and intraoperative data. However, eight patients were excluded from the postoperative data analysis (three GA patients and two PNB patients due to loss of follow-up, in addition to the three PNB patients who were converted to GA due to PNB failure). These latter patients were not considered in either of the two groups due to the acquisition of the two anesthetic techniques (PNB and GA) in order to avoid bias in data analysis.

The study groups were similar with respect to gender distribution, age, height, weight, body mass index, Shackelford's classification grade, and duration of surgery (Table I). Twenty-three PNB patients requested sedation with midazolam for performance of the block. Seven of the PNB patients received supplemental propofol during the surgical procedure and of these seven patients, three patients were converted to GA due to block failure (Table I).

Postoperative VAS pain scores at rest, on sitting, and during walking were significantly lower in the PNB group compared to the GA group ($P < 0.0001$, Figure 2). Opioid consumption was also significantly lower in association with PNB compared to GA throughout the follow-up period ($P < 0.0001$, Figure 3). In addition, pudendal nerve block patients experienced significantly shorter periods (days) of pain associated with walking, sitting and defecation compared to GA patients (Table II).

No differences were observed between groups with respect to postoperative complications such as postoperative nausea and vomiting, urinary incontinence or readmission due to severe pain (Table II). Pudendal nerve block patients were discharged from hospital more quickly than GA patients ($P < 0.0001$, Table II). In addition, PNB patients resumed normal activities more rapidly in comparison to GA patients ($P < 0.0001$, Table II). Patient and surgeon's satisfaction responses are presented in Table II.

TABLE II Postoperative outcome measures

	GA (n = 37)	*PNB (n = 35)*	*P-value*
Surgeon's satisfaction (*n/%*)	NA	34 (97.1%)	NA
PONV (*n/%*)	5 (13.5%)	1 (2.9%)	NS
Urinary retention (*n/%*)	8 (21.6%)	0	0.004
Urinary incontinence (*n/%*)	0	2 (5.7%)	NS
Readmission due to severe pain (*n/%*)	3 (8.1%)	0	NS
Duration of hospital stay			
Outpatient (*n/%*)	3 (8.1%)	25 (71.4%)	
One day (*n/%*)	22 (59.5%)	10 (28.6%)	0.0001
≥ 2 days (*n/%*)	12 (32.4%)	0 (0%)	
Pain on walking (days) mean (SD)	5.4 (6.7)	1.3 (1.9)	0.001
Pain on sitting (days) mean (SD)	6.3 (7.2)	1.0 (2.1)	0.001
Pain at defecation (days) mean (SD)	21.7 (26.6)	4.5 (6.8)	0.001
Resumption of normal activities (days)			
Mean (SD)	13.8 (7.4)	7.2 (3.4)	0.0001
Median (min-max)	15 (5–41)	7 (1–15)	
Postoperative patient satisfaction			
Satisfied (*n/%*)	9 (24.3%)	30 (85.7%)	
Moderate (*n/%*)	10 (27.0%)	4 (11.4%)	0.0001
Unsatisfied (*n/%*)	18 (48.7%)	1 (2.9%)	
Would request PNB again (*n/%*)	12 (32.4%)	33 (94.3%)	0.0001
Would recommend PNB to others (*n/%*)	11 (29.7%)	32 (91.4%)	0.0001

GA = general anesthesia; PNB = pudendal nerve block; PONV = postoperative nausea and vomiting; NA = not applicable; NS = not significant.

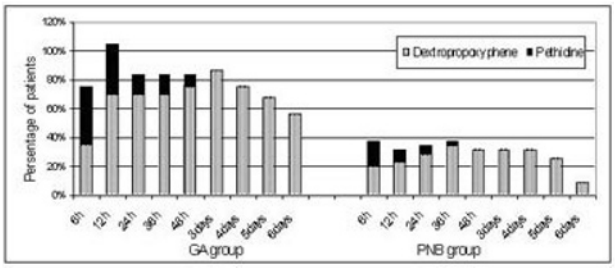

FIGURE 3 Postoperative consumption of opioid analgesics during the first six postoperative days. General anesthesia (GA; $n = 37$), pudendal nerve blockade (PNB; $n = 35$). A significantly lower requirement for supplemental opioids was observed in the PNB group throughout this time period ($P < 0.001$).

Discussion

The major finding of the study is that nerve stimulator guided PNB, with or without supplemental sedation, achieves satisfactory surgical conditions in the majority of patients undergoing hemorrhoidectomy. Furthermore, PNB is associated with prolonged postoperative analgesia, reduced consumption of opioid medications and other analgesics, and a shorter length of hospital stay. The PNB technique is associated with earlier times to resumption of normal activities compared to GA, and high overall patient satisfaction.

The results of this investigation corroborate the findings from our previous study,[8] and demonstrate that hemorrhoidectomy can be performed successfully in either awake or moderately sedated patients. Although the benefits of performing hemorrhoidectomy without general anesthesia may be of modest overall importance in otherwise healthy individuals, patients with associated co-morbidities, including cardiopulmonary disease, could potentially benefit from this regional anesthetic option.

A striking observation was the duration of analgesia, as pudendal block produced a clinically significant reduction of postoperative pain, both at rest and on activity, for up to six days postoperatively. Relief of pain during defecation post-hemorrhoidectomy, frequently described as "passing bits of broken glass"[14] would be especially important to these patients.

Improved analgesia associated with a pudendal block, compared to a more traditional approach, resulted in several secondary benefits, including lower requirements for analgesic medications, earlier discharge from the hospital, and a shorter time to resumption of normal activities. The advantage of hemorrhoidectomy as an outpatient procedure, and facilitating an earlier return to work with this technique, benefit the patient and the health care system. Furthermore, patient satisfaction is of increasing importance in many health care systems. Ratings of overall satisfaction and willingness to have the same anesthetic regimen again were significantly greater amongst pudendal block patients, compared to subjects who received GA and opioids.

The large difference between study groups with respect to both the incidence and duration of postoperative pain at rest, and during activity, deserve careful consideration. Since the duration of pain relief associated with PNBs considerably exceeded the expected duration of the local anesthetic component of the mixture used for the block (five to six hours), effective blockade of afferent pain impulses during the surgical procedure and the early postoperative period may have achieved a pre-emptive analgesic effect. Such an effect could be the result of a reduction in nociceptive plasticity within the central nervous system (i.e., reduced wind-up, reduced recruitment of silent nociceptive neurons).[15,16] Another possible factor could have been

a more local effect at the level of the injured perianal nerves. Both Gianonni *et al.*[17] and Lavand'homme and Eisenach[18] have described the potent effects of peripheral administration of a mixture of local anesthetics and clonidine when injected close to injured nerves or nerve endings. Opioid medications added to local anesthetic solutions have also been shown capable of prolonging the duration of peripheral nerve blocks.[19,20]

There are several limitations associated with the PNB technique and study design. First, despite improved precision of nerve blocks achieved with nerve-stimulation guidance, conversion to GA was required in 7.5% of patients. It is likely that block failure rates could have been improved if the blocks had been systematically repeated at any of the four injection points which demonstrated only partial loss of sensation to a pin-prick test. For this study, we injected the posterior and anterior points just once. Gabrielli *et al.*[4] reported a 100% success rate associated with PNB in a series of over 400 patients, where repeated small anesthetic injections were performed amongst the deep and superficial planes, as required, during the operation. With respect to study design, it is difficult to achieve adequate blinding when comparing GA to a regional technique. In an attempt to address this problem, the first postoperative assessment by the blinded research nurse was delayed until six hours after completion of surgery. However, it may have been possible even at this point for the trained observer to have predicted to which treatment group the patients belonged. Finally, the design did not take into consideration potential benefits accrued by local anesthetic supplementation for patients who receive general anesthesia, a technique commonly practiced at some centres.

In summary, this clinical trial demonstrates that PNB presents an effective alternative to GA for hemorrhoidectomy. Measures to reduce our observed 7% failure rate are suggested. The described regional technique is associated with reduced postoperative pain, a shorter duration of hospital stay, high patient satisfaction, and an earlier resumption of normal activities in comparison to GA for this procedure.

Acknowledgements

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