

ORIGINAL PAPER

Homeopathic *Arnica montana* for post-tonsillectomy analgesia: a randomised placebo control trial

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Objective: To evaluate the efficacy of Homeopathic *Arnica* in reducing the morbidity following tonsillectomy

Methods: Randomised double blind, placebo controlled trial at a tertiary referral centre. 190 patients over the age of 18 undergoing tonsillectomy were randomised into intervention and control groups receiving either *Arnica* 30c or identical placebo, 2 tablets 6 times in the first post-operative day and then 2 tablets twice a day for the next 7 days. The primary outcome measure was the change in pain scores (visual analogue scale) recorded by the patient on a questionnaire over 14 days post-operatively; Secondary outcome measures were: analgesia consumption, visits to the GP or hospital, antibiotic usage, the day on which their swallowing returned to normal and the day on which they returned to work.

Results: 111 (58.4%) completed questionnaires were available for analysis. The *Arnica* group had a significantly larger drop in pain score from day 1 to day 14 (28.3) compared to the placebo group (23.8) with $p < 0.05$. The two groups did not differ significantly on analgesic consumption or any of the other secondary outcome measures (number of post-operative visits to GP, use of antibiotics and secondary haemorrhage readmissions).

Conclusion: The results of this trial suggest that *Arnica montana* given after tonsillectomy provides a small, but statistically significant, decrease in pain scores compared to placebo. *Homeopathy* (2007) 96, 17–21.

Keywords: homeopathy; surgery; pain management; tonsillectomy

Introduction

Tonsillectomy is one of the most commonly performed elective operations in the UK accounting for 20% of all the operations performed by the ENT surgeons.¹ The main indication for tonsillectomy is recurrent tonsillitis, although it can also be performed for snoring, obstructive sleep apnoea and for the diagnosis of tonsillar malignancies. The operation is associated with significant morbidity, primary and secondary haemorrhages being the most dangerous complications.^{2–4} Tonsillectomy

leaves the patient with raw areas in the oropharynx. It leads to significant swelling and bruising, causing pain and difficulty in swallowing. The nature and course of this pain is well defined.⁵

Arnica montana is used for treating wounds and injuries on account of its supposed abilities to control bruising, reduce swelling, and promote recovery.^{6,7} It is one of the widely used homeopathic preparations and is popular with patients undergoing surgery.⁸ *Arnica* has effectively reduced the pain and stiffness due to arthritis of the knee.⁹ It also significantly decreased the bleeding time in another randomised, placebo-controlled, crossover study.¹⁰

The sequelae of tonsillectomy, characterised by pain and possible bleeding, appear to be an ideal setting to test the effects of *Arnica*. The aim of this study was to

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determine if homeopathic *Arnica* had a therapeutic effect when used post-operatively in tonsillectomy patients.

Materials and methods

Patients over the age of 18 undergoing tonsillectomy at Leicester Royal Infirmary between November 2002 and June 2003 were asked to participate in the study. Patients who had tonsillectomy in combination with other surgery (eg uvulopharyngopalatoplasty) were excluded, as were those undergoing tonsillectomy for a potential malignancy. Homeopathy is thought to work by stimulating the subjects' immune system and therefore patients on systemic steroids or antihistamines were also excluded.

Tonsillectomies were performed by different surgeons, but all by blunt dissection. Bipolar diathermy and/or ligatures were used to achieve haemostasis. Intra-operative analgesia, administered by various anaesthetists, was morphine 10 mg and/or a non-steroidal analgesic (ketolorac or diclofenac). All patients were discharged on the first post-operative day. All patients were sent home with standardised analgesia of Cocodamol (8/500) two tabs six hourly as required and diclofenac 50 mg eight hourly as required (unless contraindicated by severe asthma or peptic ulcer disease).

The patients were given a randomly numbered (computer generated code held by independent pharmacist) bottle containing either the *Arnica* or placebo tablets. The patients were instructed to take 2 tablets 6 times on the first post-operative day and then 2 twice a day for the next 7 days. The tablets were sucrose impregnated with *Arnica* 30C, the placebo tablets were identical sucrose tablets but not coated impregnated with Ethanol only. Both patient and prescribing doctor were blind to the identity of the tablets. The bottles containing the tablets were identical except for the identification number.

The patients filled in a daily pain visual analogue scale of 0–50 mm and a score was recorded at the end of every day for the 14 days following the surgery. The number of cocodamol and diclofenac tablets consumed each day for 14 days post-operation was also noted. The primary outcome measure was the change in pain scores, as measured by the visual analogue scale, over the post-operative days 1–14, in the placebo and *Arnica* groups. Additional analyses were done on the analgesia consumption, number of visits to the general practitioner or hospital, use of antibiotics, the day on which swallowing returned to normal and the day of return to work.

A preliminary power analysis of the pain scores was carried out using a previous paper on post-operative tonsillectomy pain as a model.⁵ A 10% difference in pain scores between the two groups was empirically decided to be clinically significant. Using this premise, we calculated that to show this 10% difference between the two groups, we would require 54 patients in each arm (85% Power).

Once all the data had been collected, the code for the randomly numbered bottles were revealed to the researchers. The results were then analysed using SPSS statistical software. The pain scores and analgesia consumption were parametric data and therefore Student's *T*-test was used to compare the two groups. The non-parametric data (day of return to work and day of normal swallowing return) were analysed using the Wilcoxon signed rank test, to find any difference between the *Arnica* and placebo groups. A chi-squared test was used to determine if there were any differences between the two groups in terms of the incidence of complications (haemorrhage, GP visit and antibiotic use).

Results

190 patients were recruited to the trial and 111 completed questionnaires were received (58.4%).

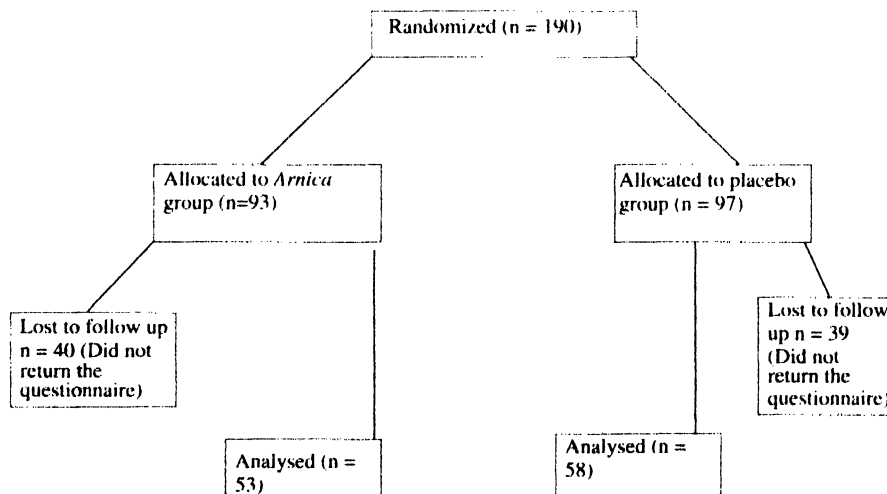


Figure 1 Flow diagram through the various stages of the trial.

The remaining 41.6% of patients did not respond (Figure 1). 73 of the respondents were female and 38 male. The *Arnica* group contained 53 patients and 58 were in the placebo group. The mean age for patients in the *Arnica* was 29.5 (range 18–63) and in placebo 27.7 (range 16–56) (no significant difference).

Pain scores

The total decrease in mean pain scores from day 1 to day 14 was 28.3 in the *Arnica* group and 23.8 in the placebo group (Table 1). The *Arnica* group had a significant total reduction in the mean pain scores ($p < 0.05$). The *Arnica* group's pain scores were significantly lower than the placebo group scores on days 10, 11 and 14 ($p < 0.05$). On all the other days there were no significant differences in pain scores, although there was a trend for the *Arnica* group to have higher pain scores on days 1–8 and lower pain scores from day 9 onwards.

Analgesia consumption

A. Cocodamol consumption

No significant differences in daily Cocodamol consumption were found between the two groups (Table 2). The mean total of Cocodamol tablets taken over the 14 days was 65.8 for the *Arnica* group A and 61.2 in the placebo group B (no significant difference)

B. Diclofenac consumption

No significant differences in daily Diclofenac consumption were found between the two groups (Table 3). The mean total of Diclofenac tablets taken over the 14 days was 24.2 for the *Arnica* group and 25.3 in the placebo group (no significant difference).

Complications

A. GP visits

57.6% of patients in the *Arnica* group and 62.1% in the placebo group visited their GP, in the 2 weeks following tonsillectomy (no significant difference).

B. Antibiotics usage

41.5% of patients in the *Arnica* group and 44.8% in the placebo group required a full course of antibiotics post-operatively (no significant difference).

C. Secondary haemorrhage

Two patients in the *Arnica* group (53 patients) and 4 patients in the placebo group (58 patients) were readmitted with secondary post-tonsillectomy haemorrhages. The secondary haemorrhage readmission rate was therefore 3.7% in the *Arnica* group and 6.8% in the placebo group. The difference was not statistically significant on a chi-square test ($p = 0.78$).

Return to work

The median day for returning to work was day > 14 in both groups (no significant difference). Range was 4 to > 14.

Table 1 Daily mean pain scores

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<i>Arnica</i> mean pain score (standard deviation)	33.8 (9.5)	34 (8.2)	34.7 (10.1)	33.8 (10.8)	36.2 (9.9)	34.8 (10.7)	31.2 (11)	26.2 (12.5)	21.1 (10.9)	15.1* (9.5)	11.5* (8.7)	9.7 (9.0)	7.9 (7.1)	5.5* (6.8)
Placebo Mean pain score (standard deviation)	32.9 (11.3)	34 (12.2)	33.9 (10.6)	32.7 (11.5)	32.9 (12.4)	33 (12.1)	29.5 (12.9)	26.1 (12.3)	22.9 (12)	19.1* (12)	15.1* (12.2)	12 (11.3)	10.4 (12.2)	9* (11.4)

Mean drop in pain scores from day 1 to 14 in *Arnica* and control groups were 28.3 and 23.8, respectively ($p < 0.05$).

*Significant difference in pain scores between the two groups ($p < 0.05$).

Table 2 Daily cocodamol consumption

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<i>Arnica</i> Mean tablets consumed (standard deviation)	6.2 (2.5)	6 (2.8)	6.3 (2.5)	6 (2.6)	6.5 (2.5)	6.1 (2.7)	5.5 (3.1)	5.2 (3.2)	4.7 (3.2)	3.9 (3.1)	3 (3.1)	2.5 (3.1)	2.2 (2.9)	1.7 (2.8)
Placebo Mean tablets consumed (standard deviation)	5.7 (2.2)	6 (2.3)	5.9 (2.5)	5.8 (2.4)	5.9 (2.7)	5.6 (2.7)	5.4 (2.9)	5 (2.8)	4.5 (2.8)	3.6 (2.7)	2.7 (2.8)	2.2 (2.6)	1.7 (2.4)	1.2 (2.1)

Mean total cocodamol consumption: *Arnica* 65.8; Placebo 61.2.

No significant differences.

Table 3 Daily diclofenac consumption

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<i>Arnica</i> mean tablets consumption (standard deviation)	2.4 (1)	2.5 (1.1)	2.6 (0.8)	2.6 (0.9)	2.6 (0.9)	2.5 (1)	2.2 (1.2)	1.9 (1.3)	1.6 (1.3)	1.2 (1.3)	0.8 (1.2)	0.5 (1.1)	0.5 (1)	0.4 (1)
Placebo mean tablets consumption (standard deviation)	2.2 (1)	2.6 (0.9)	2.5 (0.9)	2.6 (0.8)	2.7 (0.7)	2.5 (1)	2.4 (1)	2 (1.2)	1.8 (1.2)	1.5 (1.3)	0.9 (1.2)	0.7 (1.1)	0.5 (0.9)	0.4 (0.9)

Mean total diclofenac consumption: *Arnica* 24.2; Placebo 25.3.

No significant differences.

Return of normal swallowing

The median day for swallowing to return to normal was day 13 in the *Arnica* group and day 12 in the placebo group (no significant difference).

Discussion

Arnica therapy has been studied in patients who have undergone various surgical procedures; particularly dental extraction with positive results reported in some trials.¹¹⁻¹³ However a trial by Kaziro *et al*,¹⁴ of better methodology, found *Arnica* was worse than placebo for pain control and swelling after wisdom teeth extractions. Hart *et al*¹⁵ performed a randomised control trial of *Arnica* for pain and infection after total abdominal hysterectomy (73 subjects). They found no difference between the groups. A study of 37 patients who underwent carpal tunnel release surgery found that *Arnica* produced lower pain scores than placebo; however there were insufficient numbers in the trial and the difference was not significant.¹⁶ Stevinson *et al*, in a randomised placebo controlled trial, did not demonstrate any benefit using *Arnica* in the post-operative pain, bruising and swelling in patients undergoing elective hand surgery.¹⁷ Ernst *et al*¹⁸ examined eight studies involving homeopathic *Arnica* (4 with positive results and 4 with negative results) and concluded that these studies had methodological flaws and that *Arnica* is no better than a placebo. But this review could not 'prove a negative' result due to *Arnica* usage.

Our study indicates that *Arnica montana* works better than a placebo in certain respects. Unfortunately there was a high incidence of non-return of questionnaires in the trial (42%). This may be because the questionnaire was too long (three pages). Ideally we would have done an 'intention to treat' analysis including those who did not return their questionnaires, but since we had no values for them we carried out a per protocol analysis only. There were however sufficient numbers of patients to ensure adequate statistical power. There was no significant age difference between the groups. Nearly two thirds were female patients but this was expected because tonsillectomy is performed more frequently on females than males.¹

The *Arnica* group in our study experienced daily reduction in pain scores from day 1 to day 14. We found post-operative pain declined from a maximum at around the fifth day, this correlates closely to previously published patterns of post-tonsillectomy pain.⁵ The *Arnica* arm of our study showed a significantly larger drop in pain scores from day 1 to day 14. From day 9 to day 14 of the study there was a trend for the *Arnica* group to have lower pain scores than the placebo group although the difference was only significant on days 10, 11 and 14. The *Arnica*/placebo tablets were only taken for the first 8 post-

operative days and it is interesting that the largest changes in pain scores occurred after the tablets were being consumed. During the treatment period the *Arnica* group had higher mean pain scores (although not statistically significant)

If the homeopathic remedy provided good pain relief, one would expect the consumption of Cocodamol and Diclofenac to be lower in the active treatment group. No such difference was noted. The *Arnica* group, on average, consumed slightly more Cocodamol than the placebo group. Conversely the placebo group had higher overall Diclofenac consumption over the 2 week period. None of the differences in analgesia consumption were statistically significant. In light of these findings, we can be certain that the changes seen in the pain scores were not due to differential Cocodamol or Diclofenac consumption

The number of GP visits and use of antibiotics were higher than might have been expected in both groups. The majority of patients visited their GP in the 2 weeks following their surgery and over 40% in both groups were prescribed a course of antibiotics. Surgeons rarely follow-up patients who have undergone tonsillectomy and therefore perhaps do not fully recognise the extra burden that this operation places on GPs. In our trial, the numbers of patients visiting their GPs or using antibiotics were both marginally less in the *Arnica* group than the control group, but the difference was not statistically significant.

Although the number of patients readmitted to hospital with a secondary post-tonsillectomy haemorrhage was consequently lower in the *Arnica* group, the difference was not significant. A much larger trial would be needed to demonstrate any significant difference because secondary haemorrhage is a rare event. Secondary haemorrhage is attributed to bacterial infection. One previous study¹⁹ found that *Arnica* has no anti-bacterial properties therefore it is not surprising that we found no difference between *Arnica* and placebo in secondary haemorrhage rates. However, it should also be noted that even studies which used prophylactic antibiotics for tonsillectomy have found no reduction in the incidence of secondary haemorrhage.²⁰

At 14 days post-tonsillectomy, most patients in this trial had not returned to work. The date at which patients felt their swallowing had return to normal was also nearly 2 weeks post-tonsillectomy. These findings emphasise how much morbidity is associated with this procedure. We found no significant differences between the two groups relating to return to work or return of normal swallowing.

We believe that this trial was methodologically sound: sufficient patients were recruited to each arm, the randomisation process was robust and the double blinding effective. However there are some shortcomings. We were unable to perform an 'intention to treat' analysis. Ideally the operation should have been carried out by the same surgeon and anaesthetist,

unfortunately this was not logistically possible. Tonsillectomy was performed by a standard technique in all cases and we feel that any variance caused by different operators was small. The intra-operative analgesia was not rigidly controlled. We found it impossible to achieve a consensus among our anaesthetists on the optimum intra-operative analgesia and we therefore had to allow them some leeway in their choice of analgesia. However, each patient was studied over a period of 2 weeks and all post-operative analgesia was standardised, so we feel confident that any differences caused by intra-operative analgesia would be minimal and certainly could not explain changes seen in the later post-operative periods.

Our results demonstrate that *Arnica montana* given after tonsillectomy provides some benefits. There is a small but significantly greater reduction in pain scores in the second week post-tonsillectomy. The greater drop in pain scores over the 2 week period suggests that *Arnica* may speed up the post-operative recovery slightly. On the other hand, we found no difference in analgesia consumption, complications and return to normal activities. We conclude that homeopathic *Arnica montana* has a small beneficial effect when taken after tonsillectomy.

Statement of Conflict of Interest

All authors declare that they have no competing interests.

Acknowledgements

Mr Alasdair Robertson is the guarantor. He performed the procedure, conducted the trial and wrote the results section. Mr R Suryanarayanan charted on excel the patient's responses, analysed the results, reviewed the literature and wrote the introduction and discussion, with contributions from the other two authors. Mr Anil Banerjee is the Consultant responsible for patient care and supervised the trial and reviewed and modified the paper.

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