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A retrospective study on comparing the surgery and microneedles radiofrequency and microwaves treatment in axillary osmidrosis

Running title: A comparative study in axillary osmidrosis

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Abstract

Objective: To compare the traditional treatment of minimally invasion surgery with the evolving treatments of microneedles radiofrequency and microwaves, this study mainly focused on the clinical efficacy and the incidence rate (IR) of complications among three treatments.

Methods: From August 2017 to August 2018, a total of 76 patients with bilateral axillary osmidrosis were enrolled respectively underwent minimally invasion surgery, microneedles radiofrequency and microwaves treatment. All these subjects were

evaluated the clinical outcomes and collected the complications by themselves or physicians. The difference of objective recovery or effective rate, subjective effective rate, the intense of sweat secretion or armpits hair, IR of complications among these three groups were studied.

Results: The baseline characteristics of 33 patients in surgery group, 24 patients in microneedles group and 19 patients in microwaves group were similar. Firstly, the objective clinical efficacy was similar, but the subjective effective rate in surgery group was the soundest. In addition, the reduction of sweat secretion was homologous in three group, but the intense of armpits hair reduction in microneedles group was the minimum in three groups. Moreover, surgery treatment caused the highest IR of complications and the broadest types of complications, especially for the IR of 87.9% in postoperative scar formation. Meanwhile, the microwaves treatment had the best safety profile. At last, the recurrence rate on 6 months postoperatively was also identical with no significant difference.

Conclusions: For the advantages and disadvantages of these three treatments, axillary osmidrosis patients should choose the proper therapy with comprehensive considerations.

Keywords: Axillary osmidrosis, Minimally invasive surgery, Microneedles radiofrequency treatment, Microwaves treatment, Treatment

Introduction

Axillary osmidrosis is an unpleasant disorder characterized by odour elimination. It is caused by the coordination between abnormal increasing activity of apocrine glands and local homing bacterial[1]. This phenomenon is common in post-pubertal people companied with familial transmissibility, which would relief to some extent after aging[2]. Although the axillary osmidrosis odour is not considered as serious illness, the impact on physical, physiology and society life is inconvenient and terrible for patients[3]. Nowadays, effective treatments of axillary osmidrosis pursued are not only for permanent effect but for the safe solution.

The most traditional treatment for axillary osmidrosis is surgery therapy, whose effectiveness is validated by long time practice[3, 4]. The basic principle of surgery is ablation of apocrine gland through various types of operative method, such as tumescent superficial liposuction, axillary curettage and surgical sympathectomy[5, 6, 7]. To lessen the complications, minimal invasion surgery is the first selection for axillary osmidrosis[8, 9]. As well, some improvement of surgical and nursing technology are employed in surgery to reduce the incidence rate (IR) of postoperative scar, hematoma and recurrence of burning symptoms[10, 11, 12, 13]. Moreover, the microneedles radiofrequency treatment, conducted by emission of electrical heat, could directly deep to the subcutaneous tissues and cause the gland damage by array of punctures[14, 15]. Another evolving minimally invasion technique is microwaves treatment reached the goal of subcutaneous high-energy heat in similar with radiofrequency, which aroused the heat through rotating the diploe molecules of water

or sweat[16, 17]. In summary, microneedles treatment could protect the superficial epidermis from burning through inserting to deep dermis[18, 19], and microwaves treatment could specially target to the apocrine gland to avoid injuring other skin and subcutaneous tissues[8, 20, 21, 22]. These two devices had been accepted by more and more physicians, and their curative effect had been demonstrated in some randomized control trials[1, 23, 24].

The development of treatment regime in axillary osmidrosis is essential for better prognosis with safety profile[25]. For the short history of microneedles and microwaves treatment of axillary osmidrosis in China, the comparison with surgery on clinical effectiveness and adverse events is deserved a profound study. So we retrospective observe the axillary osmidrosis patients in Xinqiao Hospital affiliated to the third military medical university to compare the objective and subjective effective rate, recurrence rate and the IR of complications among patients underwent surgery, microneedles or microwaves treatments.

Materials and Methods

Patient Characteristics

In this retrospective case series from August 2017 to August 2018, a total of 76 patients with bilateral axillary osmidrosis come from Department of dermatology and rheumatology immunology of Xinqiao Hospital affiliated to the third military medical university hospital were enrolled, including 33 patients underwent minimally invasion surgery, 24 patients underwent fractional microneedles radiofrequency treatment

(microneedles) and 19 patients underwent microwaves treatment. Patients with history of axillary osmidrosis operation (minimally invasion surgery treatment, microneedles radiofrequency treatment, microwaves treatment, miradry, the patients who recieved botulinum toxin injection within 6 months), severe internal diseases (active inflammatory disease, diabetes mellitus, hypertension, chronic nephritis, bronchitis, tuberculosis, etc.), an infection in the axillary area, a propensity for keloid formation, coagulation dysfunction, and women at menstrual period were excluded. The present study was carried out in accordance with the Declaration of Helsinki revised in 1983. This study was approved by the Committee on Medical Ethics of Xinqiao Hospital and the informed consent was obtained from all patients.

Treatment methods

Minimally invasion surgery treatment

The patients were laid in supine position, with the upper arms abducted to 110°. Armpit hair was shaved and 1 cm beyond the outline of bilateral armpits hair line were marked. The anesthetic composed of 100 ml of normal saline, 1 ml/mg epinephrine, 400 mg of 2% lidocaine was used for local anesthesia. 50-60 ml of anesthetic was injected in axilla by long spinal needle and gentle press was applied to help the absorption of anesthetic. Blunt dissecting scissors were inserted at both sides of each axilla, to tunnel the subcutaneous tissues until the elevated flap thinned and softened (approximately 4-5 mm). Stroke movement was performed for effective curettage and the color of skin may become purple to red with some yellow fat particles emerged. Repeatedly wash this subcutaneous lacuna by saline and additional

curettage should be done to completely remove the remaining subcutaneous tissue fragments and fat particles and fluid. After the procedure, the stab incisions are sutured with nylon and bulky compressive dressings to prevent hematoma or seroma. After 24 hours, changed the dressing and observed the wound situation. Then changed the dressing and observed the wound situation every three days until taking out the stitches on the tenth days after operation. Patients were instructed to avoid full abduction or elevation of their arms for at least 7-10 days.

Microneedles radiofrequency treatment

Preoperative preparations were the same as those of minimally invasion surgery group, and the 50-60 ml anesthetic identical with surgery treatment was injected to the range of 1.5-2 cm beyond treatment area at first. A microneedles system (Bodytite, China) was used. The radiofrequency energy was conducted through the array of microneedles with the following parameters: the depth was 3.2-3.5 mm, blocking temperature was 96 ℃ and pulse width was 2,400 milliseconds. The gender, age, skin color and thickness were suggested as bases for the selection of treatment parameters. After inducing anesthetic, an array of 80-120 microneedles penetrated the skin, emitted radiofrequency energy and pulled out immediately. The each side of bilateral axillary was wholly scanning and repeated with two rounds to totally get 300 microneedles. The preferred endpoint was when the armpits hair root became bare without the follicle structure if the armpits hair were retained by patients before the treatment. At the end of the procedure, the treated area was covered with sterile gauze and recombinant bovine basic fibroblast growth factor gel, followed by the

application of ice packs for 15 minutes. Then the treatment area were applied mupirocin and were required to avoid water for 24 hours. Dressing with bovine basic fibroblast growth factor gel and mupirocin were renewed twice or three times a day within 5 days after microneedles treatment.

Microwaves treatment

Preoperative preparations were the same as those of minimally invasion surgery group, and the 30-40 ml identical anesthetic composed of 100 ml of normal saline, 0.3 ml of 1‰ epinephrine, 10 ml of 2% lidocaine was induced before the treatment. A microwave system was used (WB-100B, Jinting, China). The microwave treatment was then administered on both axillary of the patients. The system gave out a constant energy level of 50 Watts to heat the subcutaneous tissues within 2-4 seconds. When lifting the armpits hair, the interstitial microwave applicators penetrated into the skin beneath armpits hair root for about 0.4-0.5 cm. When the punctate petechiae turned to white and solid in the treatment area, pulled out the armpits hair and repeated the same procedure on every follicles. Lastly, the treated area was covered with wet packing of gentamicin and saline for about 30 minutes, followed by application of burn cream. Packing with gentamicin and saline should be renewed once a day within 7 days after microwave treatment.

Outcome assessment

Patients were asked to follow-up at the 2^{nd}, 3^{rd}, 5^{th}, 7^{th}, 12^{th} day postoperatively to observe the wound healing condition and at the 3^{rd} month postoperatively to evaluate the clinical efficacy and complications. The scoring system was set according the

degree of odour elimination, which could be graded by physicians as scales of excellent (level zero: odour was undetectable), good (level I: odour was detectable only after some activity), fair (level II: when patients wore single clothes at room temperature without any activity, odour was detectable at less than 1 meter away from the patient) and poor (level III: when patients wore single clothes at room temperature without any activity, odour was detectable at more than 1 meter away from the patient). To reduce the systematic error, the level of odour was evaluated by same physicians at every follow-up visit. At the same time, the degree of objective clinical efficacy was evaluated as recovery (odour was undetectable with full satisfaction of patients for this treatment), improvement (a significant reduction in odour level with partial satisfaction of patients and another treatment was not required), or invalid (no significant reduction in odour level with dissatisfaction of patients and another treatment was required). The objective effective rate = (the number of recovery patients + the number of improvement patients) / the number of all enrolled patients * 100%.

The subjective clinical efficacy, including the improvement of odour elimination, sweat secretion reduction and armpits hair loss were evaluated by patient themselves by using a 10-point visual analogue scale (VAS) at baseline and 3 months postoperatively. The 10-point VAS ranged from 0 to 10, and the point 10 was set as the severity degree of odour elimination, sweat secretion or armpits hair before treatment. The subjective improvement rate = (10 - the point of severity degree after treatment) / 10 * 100%.

The postoperative complications, including abnormal cutaneous sensation (itch, pain or numb), hematoma, seroma (ecchymosis, swelling or induration), skin necrosis, local infection and postoperative scars were collected as well. The IR of any complication = the number of any complication / the number of total complications* 100%. Disease recurrence was defined as the grade of odour elimination at 6 months postoperatively was worse than at 3 months.

Statistical analysis

SPSS 22.0 software was applied for statistical analysis and $P < 0.05$ was considered statistically significant. Measurement data were presented as mean ± standard deviation (SD) and difference among three treatment groups were analyzed by one-way ANOVA test. Categorical data of response rate or IR were presented as numbers and percentages and analyzed by the $\chi 2$ - test or Fisher's exact test. Ranked data of subjective improvement of sweat secretion or armpits hair were analyzed by Kruskal-Wallis H test. The P value needed to be corrected for the comparison between every two groups, and the adjusted $P < 0.0167$ was considered statistically significant.

Results

Characteristics of patients

Of the 76 patients with bilateral axillary osmidrosis involved in this study, 12 male and 21 female patients received minimal invasion surgery, 9 male and 15 female patients received microneedles treatment, 4 male and 15 female patients received

microwaves treatment. The average age of three groups were 28.03 ± 7.61, 28.17 ± 9.16 and 26.89 ± 6.62, respectively. In term of the baseline (gender and sex) showed in Table 1, there was no significant difference among these three groups ($P > 0.05$). All enrolled patients completed the study and follow-up sessions.

Outcomes of clinical efficacy

The follow-up evaluation of clinical efficacy was conducted at 3rd month postoperatively. For the objective recovery rate, there were 39.4%, 20.8% and 15.8% patients respectively recovered through surgery, microneedles and microwaves treatment. In addition, the objective effective rate of 84.8%, 79.2% and 68.4% patients respectively showed recovery to effective results in surgery, microneedles and microwaves groups. However, the differences of these two objective clinical efficacy evaluation were with no statistical significance among three groups (Table 2). Then the comparison of objective recovery rate or effective rate between every two groups also showed none statistical significance (Figure 1a and 1b).

At the same time, the subjective clinical efficacy assessed by patients themselves were collected (Table 3). Patients in surgery group had the most satisfaction with the odour improvement than other two groups ($P = 0.046$). Otherwise, when compared with surgery group, patients in microneedles or microwaves groups only exhibited the partial satisfaction with none statistical difference (Figure 2a).

Regarding sweating reduction, most patients in microneedles group achieved the best outcome and patients in surgery or microwaves group felt considerate improvement as well without significant difference comparing with microneedles

group (P = 0.215). In terms of armpits hair loss, feedback of patients reflected that surgery could completely remove the armpits hair. However, microneedles treatment might not influence the armpits hair at all. The intense of armpits hair reduction in microneedles group was the minimum in three groups (both P < 0.001). At last, for sweat secretion reduction between every two groups, none statistical significance were showed. But the intense of armpits hair loss in microneedles group were more rare than other two groups with significant differences (Figure 2b and 2c).

Complications and recurrence

During 3 months after treatment in this study, abnormal cutaneous sensation was the main complication in microneedles group whose IR was 58.3%, much higher than the IR of 21.2% in surgery group and 0.0% in microwaves group (P < 0.001). In addition, there were five cases of hematoma (IR: 20.8%) and seven cases of seroma (IR: 29.2%) in the microneedles group, both of which were not occurred in other two groups. However, skin necrosis (IR: 12.1%) and local infection (IR: 97.0%) were only observed in surgery group for the greater surgical wound of cutaneous tissues than other two groups. At last, when postoperative scar were respectively happened with extreme low IR of 8.3% and 0.0% in microneedles and microwaves groups, nearly 87.9% patients after surgery went through the scar formation (P < 0.001), which was also showed the significant differences between the surgery group and microneedles or microwaves groups. At 6^{th} month postoperatively, there were no significant difference in the malodor recurrence with the rate of 12.1%, 20.8% and 26.3% in surgery, microneedles and microwaves groups (Table 4). When compared the

recurrence rate between every two groups, none significant differences was observed as well (Figure 3).

Discussion

For the axillary osmidrosis, surgery the traditional therapy was widely accepted[3, 4, 5, 6, 7]. However, whether the clinical efficacy and safety of new emerging technologies, containing microneedles and microwaves treatment are better than surgery or not, is worthy of more studies[14, 15, 16, 17]. In this study, we found that objective and subjective effective rates among minimal invasion surgery, microneedles and microwaves groups were parallelly similar and the most cases about complication were recorded in surgery group. For disease recurrence, there was no obvious differences existed too.

In histological opinion, apocrine gland mainly spread in the subcutaneous layer but not the dermis[26], so both microneedles and microwaves treatment could reduce the odour elimination, sweat secretion and simultaneously avoid the damage of dermis according to the corresponding mechanism of heating[18, 19, 20, 22]. As well, the similar recurrence rates among three groups meant the prolong clinical efficacy was similar and acceptable. However, the subjective evaluation by patients themselves had the distinctive outcomes, in detail, patients received surgery were more satisfactory than other two groups. The possible explanation might be owing to the strict conditions required by objective clinical efficacy, such as room temperature, quiet state and single clothes, in contrary with the complicated environment and activities

in daily life when patients were collected for their subjective feelings[10, 15, 27, 28, 29, 30, 31]. The results of subjective improvement rate well exhibited the rationale and realistic of real-world situation, which indirectly demonstrated the reliability of surgery treatment. Because for the influence of insertion depth and treated area coverage when physician operated according to the implementation experience of machines or systems, some dissatisfaction emerged in microneedles and microwaves groups. For example, patients with more subcutaneous fat or local higher dose tumescent anesthesia were demanded to increase penetrated depth[14, 15, 32], and thin patients with little subcutaneous vacuum should reduce the anesthesia volume to relief distention of skin with the marked outline shifting[20]. In our study, local tumescent anesthesia volume in microneedles was homologous with surgery group, but less was used in microwaves group.

In term of complications, the abnormal cutaneous sensation was more common in the microneedles group with statistical significance than the surgery or microwaves group, which might be caused by the electrothermal principle of microneedles treatment[15]. However, most of the abnormal cutaneous sensation in our study would disappear within two months with no serious consequence, compared with 1.75 months in surgery group and 1.77 months in microwaves group on average. Moreover, utilizing the surgical operation combined with catheter drainage could effectively lighten the massive hemorrhage and seroma, but the drainage was not available for microneedles treatment. If microneedles were not inserted into the skin vertically[14] or were set the excess depth of radiofrequency thermal zones[32, 33], the hemorrhage

and seroma were frequently occurred. In another word, the superficial wound and special target of microwaves treatment suggested the prominent safety profile, which were also evidenced by the study of Johnson and colleagues[29]. At last, surgery treatment was also faced with the higher risk of skin necrosis, local infection and postoperative scar for the greater bloody cavity companied with more economic loss[34], so the strict disinfection protocol during operation and the postoperative drainage tube placement should be well abided. Another breakthrough of our study was the microneedles treatment was recommender for some male subpopulation hoping the persistence of armpits hair.

The short follow-up time and small sample size were the limits of this retrospective single-center trial. So a prospective, multicenter, randomized clinical trial with long-term follow‐up observations was needed for further validation of the disadvantage and advantage of these three treatments in axillary osmidrosis patients.

In conclusion, axillary osmidrosis patients could comprehensively choose the proper therapy based on lifestyle demand of themselves, professional suggestion of physicians and consideration of costs.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical approval

The present study was carried out in accordance with the Declaration of Helsinki revised in 1983. This study was approved by the Committee on Medical Ethics of

Xinqiao Hospital.

Informed consent

The informed consent was obtained from all patients.

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None.

Authors' contributions

Conception and design of the research: RW, YL; acquisition of data: WW, LR, XY; analysis and interpretation of data: YL; statistical analysis: YL; drafting the manuscript: ZH; revision of manuscript for important intellectual content: RW. All authors read and approved the final manuscript.

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Table 1. Baseline characteristics of patients in surgery, microneedles and microwaves groups

Factors	Surgery (n=33)	Microneedles (n=24)	Microwaves (n=19)	P value
Gender, n (%)				0.445[a]
Male	12 (36.4%)	9 (37.5%)	4 (21.1%)	
Female	21 (63.6%)	15 (62.5%)	15 (78.9%)	
Age, years*	28.03 ± 7.61	28.17 ± 9.16	26.89 ± 6.62	0.848[b]

*: Mean ± SD.

a: P value was showed when surgery, microneedles and microwaves groups were compared by $\chi 2$- test.

b: P value was showed when surgery, microneedles and microwaves groups were compared by one-way ANOVA.

Table 2. The objective clinical efficacy in surgery, microneedles and microwaves groups

Factors	Surgery (n=33)	Microneedles (n=24)	Microwaves (n=19)	P value
Recovery, n (%)	13 (39.4%)	5 (20.8%)	3 (15.8%)	0.124 [a]
Effective, n (%)	15 (45.4%)	14 (58.4%)	10 (52.6%)	
Invalid, n (%)	5 (15.2%)	5 (20.8%)	6 (31.6%)	
Both recovery and effective, n (%)	28 (84.8%)	19 (79.2%)	13 (68.4%)	0.376 [a]

a: P value was showed when surgery, microneedles and microwaves groups were compared by $\chi 2$- test.

Table 3. The subjective clinical efficacy in surgery, microneedles and microwaves groups

Factors	Surgery (n=33)	Microneedles (n=24)	Microwaves (n=19)	P value
Malodour improvement*	90% (50%, 100%)	50% (30%, 87.5%)	50% (30%, 90%)	0.046 [a]
Sweat secretion reduction*	70% (35%, 100%)	95% (22.5%, 100%)	50% (20%, 90%)	0.215 [a]
Armpit hair loss*	100% (40%, 100%)	0% (0%, 0%) [b]	60% (30%, 80%) [c]	< 0.001 [a]

*: median (interquartile range).

a: P value was showed when surgery, microneedles and microwaves groups were compared by Kruskal-Wallis H test.

b: $P < 0.0167$ when surgery and microneedles groups were compared by $\chi 2$- test or Fisher's exact test.

c: $P < 0.0167$ when microneedles and microwaves groups were compared by $\chi 2$- test or Fisher's exact test.

Table 4. The incidence rate of compliances and recurrence rate in surgery, microneedles and microwaves groups

Factors	Surgery (n=33)	Microneedles (n=24)	Microwaves (n=19)	P value
Abnormal cutaneous sensation, n (%)				< 0.001 [a]
No	26 (78.8%)	10 (41.7%)	19 (100.0%)	
Yes	7 (21.2%)	14 (58.3%) [b]	0 (0.0%) [c]	
Hematoma, n (%)				NA
No	33 (100.0%)	19 (79.2%)	19 (100.0%)	
Yes	0 (0.0%)	5 (20.8%)	0 (0.0%)	
Seroma, n (%)				0.039 [a]
No	28 (84.8%)	17 (70.8%)	19 (100.0%)	
Yes	5 (15.2%)	7 (29.2%)	0 (0.0%)	
Skin necrosis, n (%)				NA
No	29 (87.9%)	24 (100.0%)	19 (100.0%)	
Yes	4 (12.1%)	0 (0.0%)	0 (0.0%)	
Local infection, n (%)				NA
No	1 (3.0%)	24 (100.0%)	19 (100.0%)	
Yes	32 (97.0%)	0 (0.0%)	0 (0.0%)	
Postoperative scar, n (%)				< 0.001[a]
No	4 (12.1%)	22 (91.7%)	19 (100.0%)	
Yes	29 (87.9%)	2 (8.3%) [b]	0 (0.0%) [d]	
Recurrence, n (%)	4 (12.1%)	5 (20.8%)	5 (26.3%)	0.382 [a]

a: P value was showed when surgery, microneedles and microwaves groups were compared by $\chi 2$- test or Fisher's exact test.

b: $P < 0.0167$ when surgery and microneedles groups were compared by $\chi 2$- test or Fisher's exact test.

c: $P < 0.0167$ when microneedles and microwaves groups were compared by $\chi 2$- test or Fisher's exact test.

d: $P < 0.0167$ when surgery and microwaves groups were compared by $\chi 2$- test or Fisher's exact test.

Figure legends

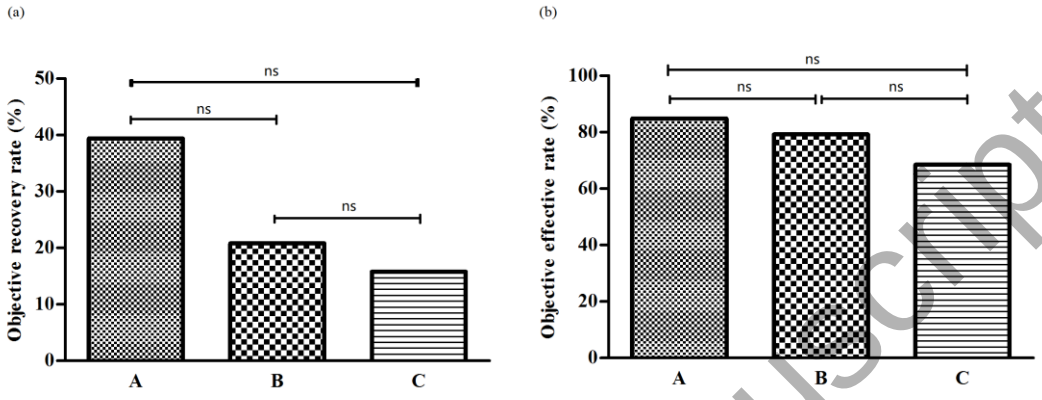

Figure 1. The objective recovery rate and objective effective rate in surgery (A), microneedles (B) and microwaves (C) groups were respectively showed. There was no statistical significances in objective recovery rate or objective effective rate between every two groups. ns: $P > 0.0167$.

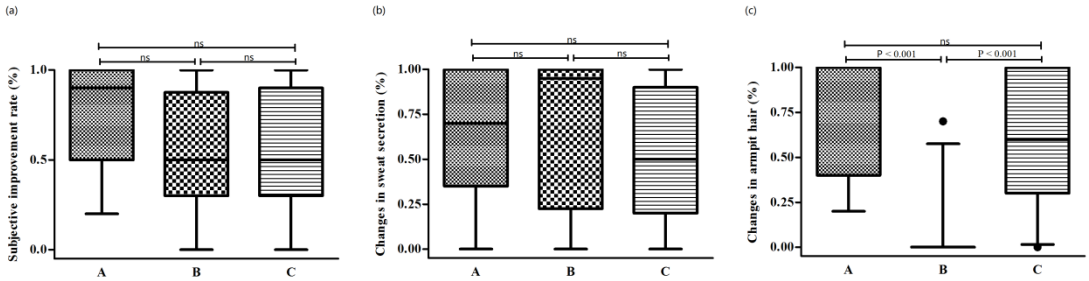

Figure 2. The subjective clinical efficacy outcomes, including the effective rate, the change of sweat secretion change and armpits hair in surgery (A), microneedles (B) and microwaves (C) groups were showed. P value in the intense of armpits hair reduction between surgery and microneedles groups or microneedles and microwaves groups was < 0.001 with statistical significances. But there was no statistical significances in subjective effective rate or the intense of sweat secretion reduction between every two groups. ns: $P > 0.0167$.

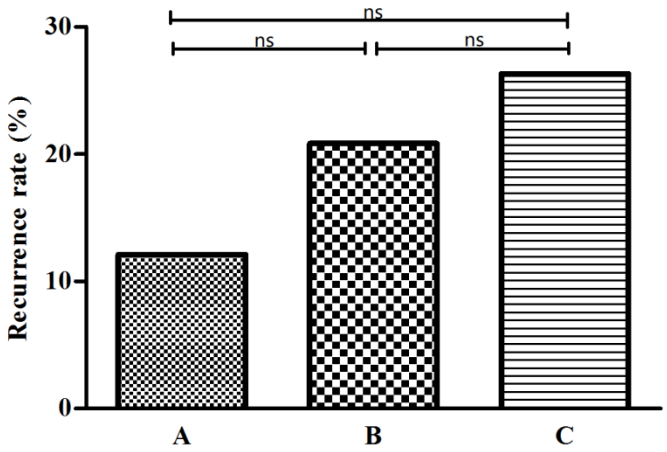

Figure 3. The recurrence rate in surgery (A), microneedles (B) and microwaves (C) groups was showed. There was no statistical significances in subjective effective rate between every two groups. ns: $P > 0.0167$.