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Research Article

Topical Honey for Wound Care After Mastectomy with Axillary Lymph Node Dissection for Breast Cancer: A Trial at Bogodogo University Hospital, Ouagadougou

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Abstract

Aims: To determine whether honey applied to the skin twice a day gives better results than povidone-iodine in managing the operative wound of women treated for breast cancer by mastectomy and axillary lymph node dissection. *Study Design:* Open-label randomized controlled trial with two parallel arms, run in one centre; the primary endpoint was judged by an assessor kept blind to the allocated treatment. *Place and Duration of Study:* The trial ran from 1 October 2024 to 30 September 2026 in the Department of Gynaecology-Obstetrics and Reproductive Medicine of Bogodogo University Teaching Hospital (Ouagadougou, Burkina Faso). *Methodology:* Adult women (18 years and above) with a histologically confirmed breast cancer, scheduled for mastectomy or conservative breast surgery combined with axillary dissection, were allocated in equal numbers to two arms; randomization was stratified by receipt of neoadjuvant chemotherapy. Once the first dressing had been taken off (day 1 or 2), the incision was treated two times a day, until it had healed completely, either with honey (honey arm) or with 10% dermal povidone-iodine (control arm). Time to complete healing was the primary endpoint; an independent assessor, unaware of the allocation, judged it from standardized photographs. The secondary endpoints comprised surgical site infection (SSI) at 30 days according to CDC criteria, seroma, skin necrosis, dehiscence, pain at the time of wound care, skin reactions and duration of hospital stay. *Results:* A total of 176 women were randomized, 88 to each arm, and 174 of them (98.9%) were followed to day 30. The arms were similar at baseline; stage III–IV disease was present in 78.2% and neoadjuvant chemotherapy had been given to 94.8%. The wound had healed completely before day 14 in 26.1% of women treated with honey against 4.7% of those treated with povidone-iodine (relative risk [RR] 5.62, 95% CI 2.03 to 15.57; $p < 0.001$); by day 21 the proportions were 93.2% and 82.6% ($p = 0.037$). An SSI was recorded in 1.1% and 7.0% of women, respectively (RR 0.16, 95% CI 0.02 to 1.32; $p = 0.063$). With honey there were fewer seromas (8.0% against 22.1%; RR 0.36, 95% CI 0.16 to 0.81; $p = 0.011$), less pain at wound care on day 7 (11.4% against 48.8%; $p < 0.001$) and fewer skin reactions (2.3% against 16.3%; $p = 0.001$). Hospital stay was of similar duration in the two arms. *Conclusion:* In women who had a mastectomy with axillary dissection, honey applied twice a day healed the wound faster than povidone-iodine and was associated with fewer seromas, less painful wound care and fewer skin reactions. SSI was also less common, although this difference was not statistically significant. Inexpensive and well tolerated, honey is a credible alternative whose benefit needs to be confirmed by a larger trial involving several centres.

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Keywords

Honey, Povidone-Iodine, Wound Healing, Mastectomy, Axillary Dissection, Breast Cancer, Surgical Site Infection, Seroma, Burkina Faso

1. Introduction

Among women, no cancer is diagnosed more often or kills more than breast cancer: in 2022, new cases were estimated at 2.3 million worldwide and deaths at over 670,000 [1, 2]. Compared with women in wealthier countries, those living in sub-Saharan Africa develop the disease earlier in life, and the tumour is usually already locally advanced when it is discovered [3, 4]. For Burkina Faso, the 2022 estimates were 1,372 incident cases and 818 deaths, and breast cancer represented 15.3% of all female cancers [1]. Local hospital-based series likewise show that most patients present late and that mastectomy is the mainstay of treatment [5].

Since patients present late and radiotherapy is difficult to obtain, the operation most often carried out for breast cancer in our context is still a modified radical mastectomy combined with clearance of the axillary lymph nodes [5, 6]. The procedure is classified as clean (Altemeier class I), yet the wound often runs a complicated course: a seroma may form, the surgical site may become infected (surgical site infection, SSI), the skin flaps may necrose or the wound may dehisce [7-10]. Published frequencies following this operation range from 21.4% to 71.1% for seroma and from 4% to 30% for SSI [11]. Such figures are higher than a clean operation should produce, and they rise further in patients who have received neoadjuvant chemotherapy, who are obese, diabetic or malnourished, or whose drains are left in place for a long time [8, 12]. When the wound fails to heal normally, patients stay longer in hospital, care becomes more expensive, and the start of adjuvant chemotherapy or radiotherapy can be postponed, which may compromise the oncological result [7, 13].

Day-to-day prevention rests on three measures: asepsis, prophylactic antibiotics and local care of the wound, for which an iodinated antiseptic, usually povidone-iodine, is generally chosen [14-16]. Whether an antiseptic should be applied again and again to a wound that is healing remains controversial. In vitro, the concentrations of povidone-iodine in common use damage keratinocytes and fibroblasts, so that tissue repair could be delayed [17]. For a surgical wound that is closed and shows no infection, existing guidelines do not advise applying an antiseptic systematically [15, 16].

The use of honey on wounds goes back to Antiquity, and there is now solid evidence that it acts against bacteria, dampens inflammation and promotes healing [18-20]. According to a Cochrane review, postoperative wounds that have become infected heal faster under honey than under an antiseptic with gauze [21]. In a recent meta-analysis pooling randomized trials of episiotomy and caesarean wounds, honey was associated with better healing and reduced pain [22]. Our own department has run a randomized trial after elective caesarean section in which honey applied two times a day brought the frequency of SSI down from 7.7% to 2.7% [23].

Where breast cancer is concerned, research on honey has dealt chiefly with fungating malignant wounds and with radiation-induced dermatitis; the findings are promising but inconsistent [24-28]. The authors of a recent systematic review could not identify a single study of honey applied to the operative wound of a mastectomy with axillary dissection, nor any study from sub-Saharan Africa [29]. That review called for a randomized comparison of a standardized honey against conventional care, in which time to healing would be the main endpoint and would be judged by a third party blind to treatment [29].

This randomized controlled trial was designed in response. Its main objective was to establish whether, in women operated on for breast cancer by mastectomy with axillary dissection, the operative wound heals completely sooner when honey is applied two times a day than when povidone-iodine is used. In addition, the two treatments were compared for SSI and other complications of the wound, duration of hospital stay, tolerance and acceptability.

2. Materials and Methods

2.1. Study Setting

Bogodogo University Teaching Hospital (CHU-B), where the study took place, is a tertiary-level facility of 400 beds in Ouagadougou, Burkina Faso, which has been operating since March 2017. Two departments operate on breast cancer there, Gynaecology-Obstetrics and Reproductive Medicine on the one hand and General Surgery on the other, and about four mastectomies are done each week. The operating team comprises seven surgeons (three gynaecological surgeons, two general surgeons and two surgical oncologists), while 88 midwives and 21 nurses look after the patients postoperatively. Medical oncology, pathology and imaging departments and a hospital pharmacy are available on site. Every oncological decision is submitted to the multidisciplinary tumour board of the hospital for validation.

2.2. Study Design and Period

We carried out an open-label randomized controlled trial in one centre, with two parallel arms to which participants were allocated in a 1:1 ratio; the assessor of the primary endpoint was blinded. Recruitment lasted 24 months (1 October 2024 to 30 September 2026), and follow-up of every participant ended 30 days after surgery. Reporting complies with the CONSORT 2010 statement [30].

2.3. Participants

Eligibility required an age of at least 18 years, a breast cancer confirmed by histology, a planned mastectomy (total or modified radical) or conservative breast surgery combined with axillary lymph node dissection performed in the department, and informed consent given in writing (by signature or fingerprint) prior to the operation.

The non-inclusion criteria were: known allergy to honey, to bee products or to iodine; known thyroid disease, pregnancy or breastfeeding, all of which are relative contraindications to iodine; a wound of Altemeier class II to IV, in particular a tumour that was ulcerated and infected when operated on; mastectomy done for palliative toilet or haemostasis; immediate reconstruction of the breast; and a home so distant from the hospital that attendance on day 30 was unrealistic.

Participants who withdrew their consent, or who had to be reoperated for a reason that had nothing to do with the wound (early haemorrhage, for instance), were excluded secondarily.

2.4. Sample Size

The calculation of the sample size was based on the primary endpoint, time to complete healing, using the formula for the comparison of two means: $n = 2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / \Delta^2$, where the two-sided α risk was set at 5% ($Z = 1.96$) and power at 80% ($Z = 0.84$), the standard deviation σ was assumed to be 6 days and the smallest difference Δ considered clinically relevant was 3 days [31, 32]. The result was 63 patients in each arm, raised to 70 to allow for 10% of losses to follow-up. The planned enrolment was nevertheless 88 patients in each arm (176 overall), so as to gain power for the secondary endpoints.

2.5. Randomization, Allocation Concealment and Blinding

A person who took no part in the care of patients produced the allocation sequence by computer, in a 1:1 ratio and in blocks of varying size (4 and 6), separately for women who had and had not received neoadjuvant chemotherapy (stratification). The assignments were kept in opaque sealed envelopes numbered in sequence; once eligibility had been verified, the next envelope was opened when the skin was being closed at the end of the operation.

The colour, smell and texture of honey made it impossible to blind patients or caregivers. Measurement bias was limited by having healing judged by an independent examiner, to whom the allocation was not disclosed, on standardized photographs taken on days 7, 11, 15, 21 and 30 once the wound had been cleaned and no trace of the product remained visible.

2.6. Interventions

Common protocol. Before surgery, each patient had her nutritional and biological status checked (haemoglobin, blood glucose, HIV serology and, where available, albumin), any anaemia was corrected, diabetes was brought under control and she took a shower. The skin of the hemithorax, the axilla and the arm on the operated side was prepared in five steps: povidone-iodine foam scrub, sterile-water rinse, drying with a sterile compress, application of 10% dermal povidone-iodine in the operating theatre, and 2–3 minutes of air-drying before the incision was made [14]. For antibiotic prophylaxis, 2 g of intravenous ceftriaxone was given at induction of anaesthesia and again when the operation exceeded four hours [15, 16].

The operation was either a modified radical mastectomy according to Patey or Madden, done through an elliptical incision, transverse (Stewart) or oblique, that took in the nipple and areola together with the biopsy scar, or a breast-conserving procedure. The axilla was cleared at levels I and II, sparing the axillary vein, the long thoracic nerve and the thoracodorsal pedicle. One suction drain was left in the axilla and, after mastectomy, another in the pectoral area. Absorbable polyglactin 2/0 was used for the subcutaneous layer; the skin was closed by a running intradermal suture, by simple interrupted stitches or by Blair-Donati stitches. The dry sterile dressing placed in theatre was taken off on day 1, or on day 2 at the latest. Each drain was withdrawn once it yielded less than 30 mL in 24 hours, and no later than day 5. Interrupted stitches were taken out between day 10 and day 14.

Honey arm (G1). Once the first dressing had been taken off, normal saline (or, at bath time, clean water and mild soap) was used to clean the wound and the skin around it, which were then dried. Honey (Melak® type) was spread in an even layer over the full length of the incision and 1 cm on either side, keeping clear of the drain sites; a dry sterile compress was laid over it and kept in place with a non-compressive bandage. This was done two times a day until the wound had healed completely. In hospital the nursing team carried out the care; after discharge it was continued by the patient herself or by a relative who had been trained, with a personal jar of honey supplied at no cost and a diary in which each wound-care session was noted.

Povidone-iodine arm (G2). Cleaning and drying of the wound were identical. Using a sterile compress, 10% dermal povidone-iodine (Betadine® dermique) was applied over the full length of the incision and 1 cm on either side, keeping clear of the drain sites, and left to dry for 1–2 minutes before a dry sterile compress was put on. As in the honey arm, care was given two times a day until complete healing, first by the

nursing team and then at home, and each patient received a personal bottle at no cost.

Follow-up. Women were examined every day while in hospital, and afterwards as outpatients on days 7, 11, 15, 21 and 30. Each visit included measurement of temperature, scoring of pain on a visual analogue scale (VAS), a search for redness, warmth, induration, discharge, seroma, necrosis and dehiscence, and standardized photography of the wound. Any discharge that looked suspicious was sampled for bacteriological examination.

2.7. Outcomes and Definitions

Time to complete healing was the primary endpoint. Complete healing meant that the whole incision had re-epithelialized and showed neither discharge, nor dehiscence, nor any remaining crust that still needed care, in the judgement of the independent assessor. The time was counted in days from the operation to the first visit at which this state was noted.

The secondary endpoints were as follows: SSI occurring within 30 days and meeting CDC criteria [33, 34] (pus draining from the incision or the drain, a microorganism grown from a sample taken aseptically, local inflammatory signs that led to the wound being reopened, or a diagnosis made by the surgeon), categorized as superficial, deep or organ/space infection; seroma, meaning a collection of fluid palpable on clinical examination beneath the flaps or in the axilla for which one or more needle aspirations were needed; necrosis of the skin, graded minor (< 1 cm, treated by local care) or major (≥ 1 cm, or needing debridement); dehiscence, meaning that the edges of the wound had separated over 1 cm or more; haematoma; duration of hospital stay; pain at wound care (VAS ≥ 4) on day 2 and on day 7; pruritus or skin reaction; adherence, i.e. at least 90% of the applications carried out according to the wound-care diary; satisfaction; and whether adjuvant treatment had begun during follow-up.

A haemoglobin concentration under 12 g/dL defined anaemia. Nutritional status was graded from the body mass index (BMI) as undernutrition when it was < 18.5, normal weight from 18.5 to 24.9, overweight from 25 to 29.9 and obesity when it was ≥ 30 kg/m^2.

2.8. Data Collection

Four trained investigators recorded the data prospectively on a standardized case-report form. Their sources were the interview and clinical examination of each patient, her medical record, the operative report, the temperature chart, the dressing register and the standardized photographs. The information gathered covered socio-demographic data, medical history and comorbidities, the cancer (side, TNM stage, histological type, grade, neoadjuvant chemotherapy), the operation (type of surgery, incision, operator, duration, blood loss and transfusion, number of drains, type of suture, lymph node count) and the outcomes.

2.9. Statistical Analysis

After entry in Excel and cleaning, the data were processed with SPSS (version 27). Every randomized patient whose 30-day follow-up was complete was analysed in the arm to which she had been assigned. For categorical variables we report counts with percentages; arms were compared using Pearson's chi-square test, replaced by Fisher's exact test in 2 × 2 tables where an expected count was under 5, and by the Fisher–Freeman–Halton exact test (Monte-Carlo estimate based on 20,000 samples) where over 20% of the expected counts were under 5. Time to healing had been recorded as ordered classes (< 14, 14–21, 22–30 and > 30 days); the Mann–Whitney U test was therefore applied to its distribution, and Fisher's exact test to the proportion of women healed before day 14 and by day 21. For binary outcomes, the effect of honey is given as a relative risk (RR) together with a 95% confidence interval obtained by the log method. Statistical significance was set at 5%.

2.10. Ethical Considerations

Approval of the protocol was granted by the Health Research Ethics Committee of Burkina Faso (Comité d'Éthique pour la Recherche en Santé, CERS) under no. 2024-07-283, dated 2 July 2024. The principles of the Declaration of Helsinki were respected throughout the trial [35]. Every patient was informed orally and in writing, in a local language if needed, before signing the consent form or marking it with her fingerprint, and she remained free to leave the trial whenever she wished with no effect on her care. All data were anonymized. Neither honey nor povidone-iodine was charged to the patients, and adverse effects, if any, were treated and reported.

3. Results

3.1. Participant Flow

Over the 24 months of recruitment, 203 women had an operation for breast cancer that included axillary dissection. Seven of them were ineligible because of breast necrosis, and a further 20, although eligible, were not randomized. The remaining 176 were randomized in equal numbers (88 and 88) to honey and to povidone-iodine, and every one of them was given the treatment assigned. Follow-up was incomplete for two women assigned to povidone-iodine (withdrawal or loss to follow-up). The analysis therefore concerned the 174 women (98.9%) followed to day 30, namely 88 treated with honey and 86 treated with povidone-iodine (Figure 1).

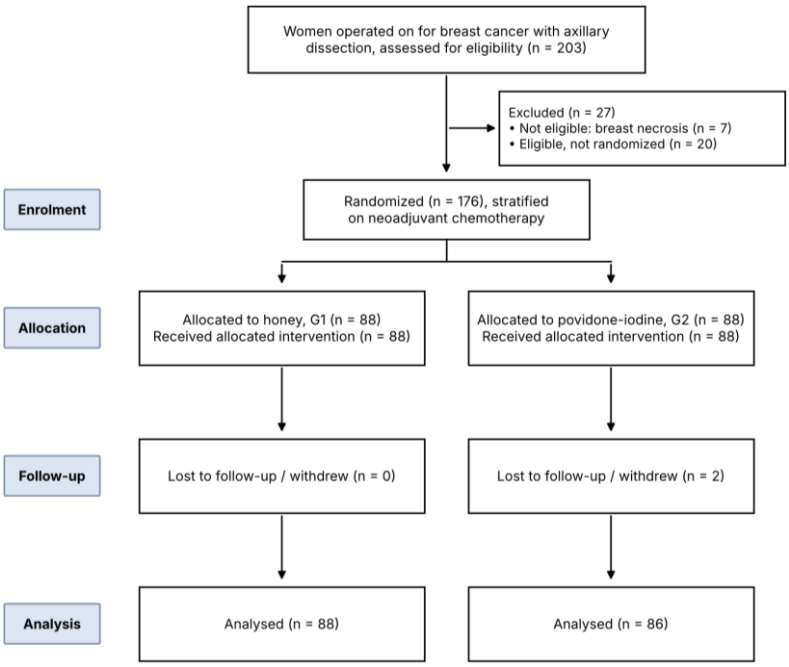

Figure 1. *CONSORT flow diagram of the trial.*

3.2. Baseline Characteristics

Participants were 56 years old on average (range 28–78). Women of 50 years and above made up 71.8% of the sample, the 50–64-year class being the most represented (48.3%). Housewives were the majority (70.1%), and about one in two women (49.4%) had reached secondary school. In all, 71.8% were postmenopausal. Undernutrition affected one woman in four (BMI < 18.5 kg/m^2: 24.7%), and few were obese (4.6%). Before surgery, 60.3% were anaemic. Most cancers were advanced, 78.2% being at stage III or IV; the histological type was invasive carcinoma of no special type in 84.5% of cases, and neoadjuvant chemotherapy had been administered to 94.8% of the women (Table 1).

Socio-demographic, clinical, oncological and operative characteristics were similar in the two arms, with two exceptions: at least one comorbidity was more common among women given honey (62.5% vs 46.5%; p = 0.047), and so, to a lesser degree, was an age of 50 years or more (77.3% vs 66.3%; p = 0.13) (Tables 1 and 2).

Table 1. *Baseline characteristics by study arm.*

Characteristic	Honey (G1) n = 88, n (%)	Povidone-iodine (G2) n = 86, n (%)	p
Age (years)			0.46[b]
< 35	2 (2.3)	4 (4.7)	
35–49	18 (20.5)	25 (29.1)	
50–64	45 (51.1)	39 (45.3)	
≥ 65	23 (26.1)	18 (20.9)	
Occupation			0.75[b]
Housewife	63 (71.6)	59 (68.6)	
Trader	12 (13.6)	16 (18.6)	
Civil servant / employee	10 (11.4)	7 (8.1)	
Informal sector	3 (3.4)	4 (4.7)	
Education			0.23[b]

Characteristic	Honey (G1) n = 88, n (%)	Povidone-iodine (G2) n = 86, n (%)	p
None	10 (11.4)	12 (14.0)	
Primary	8 (9.1)	9 (10.5)	
Secondary	49 (55.7)	37 (43.0)	
Higher	19 (21.6)	28 (32.6)	
Koranic school / literacy class	2 (2.3)	0 (0.0)	
Postmenopausal	68 (77.3)	57 (66.3)	0.13[a]
BMI (kg/m^2)			0.43[b]
< 18.5	18 (20.5)	25 (29.1)	
18.5–24.9	42 (47.7)	37 (43.0)	
25–29.9	25 (28.4)	19 (22.1)	
≥ 30	3 (3.4)	5 (5.8)	
Comorbidities			
At least one comorbidity	55 (62.5)	40 (46.5)	0.047[a]
Hypertension	24 (27.3)	31 (36.0)	0.25[a]
Diabetes	6 (6.8)	8 (9.3)	0.59[a]
HIV infection	0 (0.0)	1 (1.2)	0.49[a]
Sickle cell disease	1 (1.1)	0 (0.0)	1.00[a]
Preoperative anaemia (Hb < 12 g/dL)	56 (63.6)	49 (57.0)	0.44[a]
Smoking	0 (0.0)	3 (3.5)	0.12[a]
Stage			0.25[b]
I	0 (0.0)	2 (2.3)	
II	17 (19.3)	19 (22.1)	
III	65 (73.9)	63 (73.3)	
IV	6 (6.8)	2 (2.3)	
Histological type			0.07[b]
Invasive carcinoma of no special type	71 (80.7)	76 (88.4)	
Invasive lobular carcinoma	12 (13.6)	10 (11.6)	
Other	5 (5.7)	0 (0.0)	
Neoadjuvant chemotherapy	82 (93.2)	83 (96.5)	0.50[a]

[a] Fisher's exact test. [b] Fisher–Freeman–Halton exact test (Monte-Carlo). A patient may have more than one comorbidity.

3.3. Operative Characteristics

The operation was a modified radical mastectomy in 96.6% of women, and the incision was a transverse Stewart incision in 94.3%. In 89.7% of cases the procedure took under 90 minutes, and 5.7% of women were transfused during the operation. On average, 12.5 lymph nodes were removed from women given honey and 10.7 from those given povidone-iodine. No operative characteristic differed between the arms (Table 2).

Table 2. Operative characteristics by study arm.

Characteristic	Honey (G1) n = 88, n (%)	Povidone-iodine (G2) n = 86, n (%)	p
Type of surgery			0.68[a]
Modified radical mastectomy	84 (95.5)	84 (97.7)	
Breast-conserving surgery + axillary dissection	4 (4.5)	2 (2.3)	
Incision			0.33a
Transverse (Stewart)	81 (92.0)	83 (96.5)	
Oblique	7 (8.0)	3 (3.5)	
Skin closure			0.95[c]
Intradermal running suture	7 (8.0)	8 (9.3)	
Simple interrupted stitches	42 (47.7)	40 (46.5)	
Blair-Donati stitches	39 (44.3)	38 (44.2)	
Operative duration			0.21a
< 90 min	76 (86.4)	80 (93.0)	
90–150 min	12 (13.6)	6 (7.0)	
Operator			0.21a
Gynaecological surgeon	83 (94.3)	85 (98.8)	
Other surgeon	5 (5.7)	1 (1.2)	
Intraoperative transfusion	6 (6.8)	4 (4.7)	0.75a
Lymph nodes removed, mean	12.5	10.7	–

[a] Fisher's exact test. [c] Pearson's chi-square test.

3.4. Primary Outcome: Time to Complete Healing

Wounds treated with honey healed sooner (Table 3). Complete healing had been reached before day 14 by 26.1% of women given honey and by 4.7% of those given povidone-iodine (RR 5.62, 95% CI 2.03 to 15.57; p < 0.001), and by day 21 by 93.2% and 82.6%, respectively (RR 1.13, 95% CI 1.01 to 1.26; p = 0.037). In both arms the median fell in the 14–21-day class, yet with honey the distribution as a whole moved towards shorter healing times (Mann–Whitney p < 0.001). A single wound, treated with povidone-iodine, was still unhealed on day 30.

Table 3. Time to complete healing by study arm.

Time to complete healing	Honey (G1) n = 88, n (%)	Povidone-iodine (G2) n = 86, n (%)	Total n = 174, n (%)
< 14 days	23 (26.1)	4 (4.7)	27 (15.5)
14–21 days	59 (67.0)	67 (77.9)	126 (72.4)
22–30 days	6 (6.8)	14 (16.3)	20 (11.5)
Not healed at day 30	0 (0.0)	1 (1.2)	1 (0.6)
Healed before day 14: RR (95% CI); p	5.62 (2.03–15.57); < 0.001a		
Healed by day 21: RR (95% CI); p	1.13 (1.01–1.26); 0.037a		
Distribution of healing classes	Mann–Whitney p < 0.001		

RR: relative risk, honey vs povidone-iodine. [a] Fisher's exact test.

3.5. Secondary Outcomes

Surgical site infection. An SSI was diagnosed in seven women (4.0%), one of whom had received honey (1.1%) and six povidone-iodine (7.0%) (RR 0.16, 95% CI 0.02 to 1.32; p = 0.063) (Table 4).

Other wound complications. The complication seen most often was seroma (14.9%), whose frequency with honey was close to one third of that with povidone-iodine (8.0% vs 22.1%; RR 0.36, 95% CI 0.16 to 0.81; p = 0.011). There were only six cases of skin necrosis, five of which followed povidone-iodine (p = 0.12 for any necrosis). A single haematoma was recorded, also after povidone-iodine, and no wound dehisced.

Length of stay. Women given honey stayed in hospital for 5.3 days on average and those given povidone-iodine for 5.6 days. Discharge took place between day 4 and day 7 for 82.8% of women, and the arms did not differ (p = 0.32).

Pain, tolerance and acceptability. Fewer women given honey reported pain at wound care (VAS ≥ 4): the gap was modest on day 2 (38.6% vs 53.5%; p = 0.068) and large on day 7 (11.4% vs 48.8%; RR 0.23, 95% CI 0.12 to 0.43; p < 0.001). Pruritus or a skin reaction was noted in 2.3% of women given honey and 16.3% of those given povidone-iodine (RR 0.14, 95% CI 0.03 to 0.60; p = 0.001). Both treatments were applied as prescribed by 97.7% of women, and satisfaction was high with each (97.7% vs 93.0%; p = 0.17). Adjuvant treatment had begun before the end of the 30-day follow-up in 34.1% and 41.9% of women, respectively (p = 0.35).

Table 4. *Secondary outcomes by study arm.*

Outcome	Honey (G1) n = 88, n (%)	Povidone-iodine (G2) n = 86, n (%)	RR (95% CI)	p
Surgical site infection at day 30	1 (1.1)	6 (7.0)	0.16 (0.02–1.32)	0.063[a]
Seroma requiring aspiration	7 (8.0)	19 (22.1)	0.36 (0.16–0.81)	0.011[a]
Minor skin necrosis	1 (1.1)	4 (4.7)	–	0.21[a]
Major skin necrosis	0 (0.0)	1 (1.2)	–	0.49[a]
Haematoma	0 (0.0)	1 (1.2)	–	0.49[a]
Dehiscence	0 (0.0)	0 (0.0)	–	–
Length of stay 4–7 days	71 (80.7)	73 (84.9)	–	0.32[b]
Length of stay 8–14 days	12 (13.6)	12 (14.0)		
Length of stay > 14 days	5 (5.7)	1 (1.2)		
Pain during care (VAS ≥ 4), day 2	34 (38.6)	46 (53.5)	0.72 (0.52–1.00)	0.068[a]
Pain during care (VAS ≥ 4), day 7	10 (11.4)	42 (48.8)	0.23 (0.12–0.43)	< 0.001[a]
Pruritus / skin reaction	2 (2.3)	14 (16.3)	0.14 (0.03–0.60)	0.001[a]
Adherence ≥ 90% of applications	86 (97.7)	84 (97.7)	–	1.00[a]
Satisfied or very satisfied	86 (97.7)	80 (93.0)	–	0.17[a]
Adjuvant treatment started by day 30	30 (34.1)	36 (41.9)	–	0.35[a]

RR: relative risk, honey vs povidone-iodine. [a] Fisher's exact test. [b] Fisher–Freeman–Halton exact test (Monte-Carlo) on the three length-of-stay classes.

4. Discussion

Among the 176 women randomized after surgery for breast cancer, applying honey to the mastectomy wound two times a day led to faster healing than povidone-iodine: before day 14, about one wound in four had healed under honey, against fewer than one in twenty under povidone-iodine. Seromas, painful wound care and skin reactions were also less common with honey. Fewer infections were seen with honey as well, although statistical significance was not reached for SSI. We are not aware of any earlier randomized trial that tested honey on the operative wound of a mastectomy with axillary dissection, or of any such trial carried out in sub-Saharan Africa [29].

4.1. Characteristics of the Patients

Some 70% of our patients had reached the age of 50. They were thus somewhat older than is usual in series from sub-Saharan Africa, a region in which the disease appears 10 to 15 years sooner than in wealthier countries [3, 4]. Zongo et al., also in Ouagadougou, described a younger population, most of whom likewise presented with advanced tumours [5]. That 78.2% of our patients had stage III–IV disease reflects the late diagnosis documented by Jedy-Agba et al. [3]. Late presentation is the reason why almost all of them needed a modified radical mastectomy (96.6%) and neoadjuvant chemotherapy (94.8%), the latter being known to compromise wound healing [8]. How fragile these women were is shown by the proportions who were anaemic before surgery (60.3%) or undernourished (24.7%). Women assigned to honey were a little older, and more of them had one or more comorbidities (62.5% vs 46.5%). Yet advancing age and comorbid conditions, notably diabetes and hypertension, are among the factors most regularly linked to wound complications of mastectomy [11, 12, 36]. The imbalance was thus to the disadvantage of honey and, if it biased the result, it probably did so by understating the benefit of honey.

4.2. Wound Healing

Wounds were over five times more likely to have healed before day 14 when honey was used (26.1% vs 4.7%), and by day 21 almost every wound in that arm had healed (93.2% vs 82.6%). Such a gain fits what is known of the way honey supports healing: it keeps the wound moist, stimulates angiogenesis, the proliferation of fibroblasts and re-epithelialization, and modulates the inflammatory response [18, 37]. The comparator may have contributed too, since povidone-iodine is cytotoxic to keratinocytes and fibroblasts and could therefore hold back tissue repair [17]. These results are in line with those of the Cochrane review by Jull et al. [21] and of the meta-analysis that Ferraz Barbosa et al. devoted to obstetric wounds [22]. Bocoum et al., working in Mali, observed that caesarean wounds healed sooner under a medical-grade honey than under povidone-iodine associated with oral antibiotics [38]. By contrast, trials of honey in radiation dermatitis of the breast have frequently failed to show a significant effect [25, 26], but the skin lesion studied there is of a different nature.

The companion trial that we conducted after caesarean section, where the control arm received no topical agent, likewise found that healing times moved towards shorter values with honey [23]. Both trials thus point the same way, even if their healing times do not lend themselves to direct comparison: a mastectomy wound is longer, it is drained, and the women concerned are older, frequently anaemic or undernourished, and nearly all have had neoadjuvant chemotherapy.

4.3. Surgical Site Infection

At 4.0%, the overall frequency of SSI in this trial sits at the bottom of the published range for mastectomy with axillary dissection (4–30%) [11], despite a population in which advanced tumours, neoadjuvant chemotherapy and anaemia were the rule. The measures shared by both arms (skin antisepsis in five steps, prophylactic antibiotics and early removal of the dressing) therefore appear to have worked. Even so, clean surgery is ordinarily expected to produce about 2% of infections, a level that our figure still exceeds [7, 8].

With honey, SSI was over 80% less frequent in relative terms, a difference that matters clinically. It is biologically plausible, since honey has been shown to inhibit Gram-positive cocci, methicillin-resistant *Staphylococcus aureus* and biofilms [39-41], and honeys from West Africa are active in vitro against the pathogens found in wounds [42, 43]. Nevertheless, only seven infections occurred, so the comparison lacked statistical significance and the confidence interval is broad (0.02 to 1.32); the finding is a trend that awaits confirmation. It must also be remembered that honey was compared with an active antiseptic and not with no care at all. In view of its price, its availability and its tolerance, honey would be of practical value even if it merely equalled povidone-iodine in preventing SSI. In our caesarean trial, which enrolled more women (440) and used no topical agent in the control arm, the reduction in SSI with honey was significant (2.7% vs 7.7%) [23]. Similarly, Dryden et al. noted a fall in caesarean wound infections when an antimicrobial honey was used [44].

4.4. Seroma and Other Complications

A seroma developed in 14.9% of our patients, a proportion lower than the 21.4–71.1% compiled in Yaogo's review [11] and than the 24.2% that Crestani et al. calculated from randomized trials [10]. The gap is largely a matter of definition: we counted only seromas that had to be aspirated, a clinical criterion narrower than the ultrasound criteria adopted by many authors [11].

With honey, seromas were close to three times rarer (8.0% vs 22.1%; RR 0.36). An effect of this magnitude approaches that of flap fixation (odds ratio 0.27), which is the preventive technique with the strongest evidence [45]. We had not anticipated this result, given that a product spread on the skin has no direct action on the dead space beneath it. One possible explanation is a local anti-inflammatory action, inflammation being considered to play a part in seroma formation [11, 46]; another is that the wound edges healed better. Since the assessment of seroma was not blinded, we cannot rule out a detection bias. On the other hand, the principal risk factors for seroma, namely age, BMI, extent of surgery and operative duration, were balanced between the arms or, in the case of age, weighed against honey [9, 11]. A further trial in which seroma is measured by standardized ultrasound is needed to confirm this observation.

Necrosis of the skin was uncommon; most cases followed povidone-iodine, but the arms did not differ significantly. No wound dehisced. Hospital stay was of similar duration with the two treatments (5.3 vs 5.6 days), which is unsurprising

since patients are discharged on surgical grounds (drain output, general condition) well before the wound has healed completely. Nor was there any difference in the share of women whose adjuvant treatment had begun by day 30; whether wound care influences the time to adjuvant treatment can only be judged with a follow-up extending beyond 30 days [13].

4.5. Tolerance, Acceptability and Cost

Far fewer women found wound care painful when honey was used, above all on day 7 (11.4% vs 48.8%), and skin reactions were unusual with honey (2.3%, against 16.3% with povidone-iodine). Because honey does not stick to the wound, changing the dressing hurts less [18, 20]. The skin reactions seen under povidone-iodine correspond to the irritant dermatitis that repeated applications of this antiseptic are known to cause [17]. Adherence and satisfaction were high whichever product was used, which indicates that patients accepted the two treatments. In our context, honey has the considerable advantages of being cheap and available locally. This argues for developing a Burkinab è medical-grade honey that is standardized and quality-controlled, as an extension of the galenic work already done on honey combined with shea butter for cancer wounds. Nothing in the experimental literature indicates that honey applied topically promotes tumour growth; on the contrary, an antiproliferative action on breast cancer cell lines has been described in several studies [35, 44].

4.6. Strengths and Limitations

This trial has several strengths: allocation was randomized and concealed, randomization was stratified by neoadjuvant chemotherapy, the comparator was an active treatment that mirrors everyday practice, the primary endpoint was judged blind from photographs, definitions were standardized, 98.9% of participants were retained over the 30 days of follow-up, and the arms were similar at baseline.

Its limitations must also be acknowledged. First, neither patients nor caregivers could be blinded, a source of bias shared by every trial of honey [29]. Its impact was reduced by having healing judged blind and by defining SSI with objective criteria; seroma, pain and other secondary endpoints, however, were assessed openly. Second, the findings come from one centre and may not apply elsewhere. Third, once the women had gone home, they or a relative carried out the wound care, and the diary was our only means of estimating how well it was done. Fourth, the sample was too small to have adequate power for SSI. Finally, because healing was noted as a class at scheduled visits, neither mean healing times nor survival curves could be computed, and with so few infections a multivariable analysis of risk factors was not feasible.

5. Conclusion

In women operated on for breast cancer by mastectomy with axillary dissection, honey applied to the wound two times a day healed it faster than povidone-iodine (healing before day 14 in 26.1% vs 4.7%); seromas, painful wound care and skin reactions were less common, and acceptability was excellent. Infections were also fewer with honey (1.1% vs 7.0%), without reaching statistical significance. For the care of these wounds, honey therefore looks like an effective, safe, inexpensive and readily available substitute for povidone-iodine. A larger trial conducted in several centres and powered for SSI is required to confirm the effect on infection; it should assess seroma by ultrasound and collect individual-level data suitable for time-to-event and multivariable analyses. In parallel, a local medical-grade honey should be standardized and a cost-effectiveness analysis undertaken.

6. Consent

Written consent was obtained from every patient, in keeping with international and university standards, and the authors have retained the signed forms.

7. Disclaimer (Artificial Intelligence)

During revision of the manuscript, the authors used a generative artificial intelligence tool (Claude, Anthropic) to edit the language, to format the text, to restructure sections as requested by the reviewers and to rephrase passages. All content was then checked by the authors, who assume full responsibility for it.

Abbreviations

aOR	Adjusted Odds Ratio
ARR	Absolute Risk Reduction
CDC	Centers for Disease Control and Prevention
CHU-B	Bogodogo University Teaching Hospital (Centre Hospitalier Universitaire de Bogodogo)
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
G1	HONEY ARM
G2	Control Arm
HIV	Human Immunodeficiency Virus
NNT	Number Needed to Treat
OR	Odds Ratio
REEDA	Redness, Oedema, Ecchymosis, Discharge, Approximation
RR	Relative Risk
SSI	Surgical Site Infection

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Author Contributions

Ouattara Adama: Conceptualization, Investigation, Methodology, Project administration, Writing – original draft

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Ouedraogo Charlemagne: Investigation, Validation, Writing – review & editing

Sawadogo Yobi Alexi: Supervision, Validation, Writing – review & editing

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Conflicts of Interest

The authors declare no conflicts of interest.

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