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Deodorant pad for ulcerated breast cancer: safety and efficacy

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► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/spcare-2024-005024).

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Received 7 June 2024
Accepted 11 June 2024

To cite: Ishiba T, Ishida H, Inoue M, *et al*. *BMJ Supportive & Palliative Care* Epub ahead of print: [please include Day Month Year]. doi:10.1136/spcare-2024-005024

ABSTRACT

Objectives APOLLO study, 'efficacy and safety of the deodorAnt Pad against Odour and uLceration for LOcally advanced breast cancer', aimed to assess the safety and efficacy of wearing a deodorant pad in patients with locally advanced breast cancer (LABC) with an ulceration.

Methods Komagome Pads were previously developed by Juntendo University and Kao Corporation. In test A, a conventional pad consisting of gauze, a commercially available diaper, pad, etc and the Komagome Pad were compared over 3 days to assess their efficacy and possible improvements for short-term use. In test B, the Komagome Pad was used continuously for 1 month to evaluate its safety during long-term use.

Results This study included 14 patients in test A and nine in test B. In odour evaluation using sensory testing in test A, nine patients reported more significant efficacy in odour suppression with the Komagome Pad. The odour intensity of the Komagome Pad was lower on the gas chromatography-mass spectrometry. The group with a high level of exudation reported significantly higher satisfaction with the Komagome Pad. In test B, no adverse events were observed.

Conclusions A new deodorant pad for LABC demonstrated high safety and deodorant efficacy.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Locally advanced breast cancer (LABC) with an ulceration impairs quality of life.

WHAT THIS STUDY ADDS

⇒ The deodorant pad has been developed specifically for LABC.
⇒ Sensory testing and gas chromatography-mass spectrometry proved that these pads were effective.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This deodorant pad has been proven safe and effective.
⇒ Contributes to improving the quality of life of LABC patients.

INTRODUCTION

Locally advanced breast cancer (LABC) often leads to ulceration with bleeding, discharge and a foul odour, significantly impacting patients' quality of life. We studied 34 LABC patients with ulcers at our hospital, finding the median duration of symptoms before and after diagnosis to be one and 2.5 years, respectively.

There is currently no standardised method of locally treating an ulcerating cancer. Gauze or commercial pads are used, but the gauze or pads must be replaced frequently, and the odour often becomes an issue. Moreover, the patients have the difficulty in applying the pads unassisted and of the lack of commercially available pads. To address this omission, the Komagome Pad, a deodorant pad for LABC designed to cover the entire lesion, was developed in collaboration with Kao Corporation. Alexander reported that the odour arising from the ulcerating cancer was produced by the metabolic activity of anaerobic bacteria and fungi in their ulceration. The components of the odour were fatty acids (butyric acid, carboxylic acid, etc), amines and diamines (cadaverine, putrescine). Dimethyl trisulfide was also identified as a contributing factor.[1–3] Analysis of the odour components in LABC in the present study identified five butyric acid, isovaleric acid, diacetyl, dimethyl trisulfide and trimethylamine as the compounds contributing to odour production. Based on this finding, the Komagome Pads were designed by

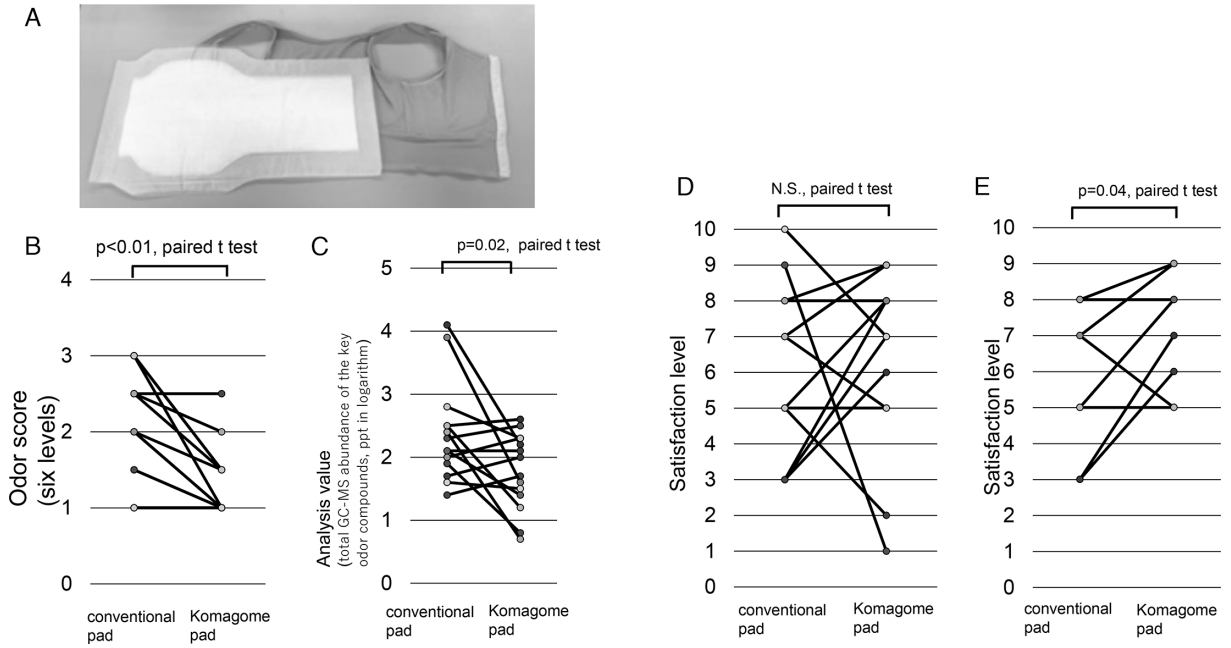

Figure 1 (A) Komagome Pad. (B) Odour evaluation by sensory testing (paired t-test). Odour intensity was lower for the Komagome Pad than for the conventional pad. (C) Odour intensity by GC-MS (paired t-test). Odour intensity was lower for the Komagome Pad than for the conventional pad. (D) Patient's satisfaction level analysed by paired t-test. No significant difference in overall. (E) Satisfaction level was significantly higher at the Komagome Pad in the high exudation group. GC-MS, gas chromatography-mass spectrometry.

combining chemical and physical deodourisers for these odour compounds.

The present study, dubbed the 'efficiency and safety of the deodorantAnt Pad against Odour and uLceration for LOcal advanced breast cancer (APOLLO; UMIN000036906) study, evaluated the safety and efficacy of the Komagome Pad in suppressing odour in patients with LABC.

PATIENTS AND METHODS

Patients

Participants were over 20 years old with LABC and ulcerating lesions, receiving treatment at Komagome Hospital between March 2019 and March 2020. Written consent was required.

The pads

The present study used the Komagome Pad developed by Juntendo University and Kao Corporation. The Komagome Pad has double-sided tape and is 49×28 cm in size and is designed to prevent axillary leakage (figure 1A). The double-sided tape was used to attach the Komagome Pad to Hugfit, a crop top designed for patients with breast cancer (Toray Corporation).

Study design

The present study comprised tests A and B (online supplemental figure 1). In the former, the conventional pad (gauze, commercially available diaper, pad, etc) and the Komagome Pad were compared for 3 days each to assess their utility and possible improvements for short-term use. In test B, the Komagome Pad was used continuously for 1 month to evaluate its safety for long-term use.

Collection of the pads and odour evaluation

In test A, both the conventional pads and the Komagome Pads were collected on day 3. In test B, sensory testing was performed to evaluate odour; two people, including one odour judge, evaluated the pads using the Kao Odour Expert Panel. The odour judge was certified under the Japanese Odour Control Law. The Kao Odour Expert Panel was used to score odour in accordance with the six levels, namely, 0: no odour, 1: odour that can only just be sensed, 2: weak odour that can be recognised, 3: slight odour by which the source can be identified, 4: strong odour and 5: intense odour.[4]

Odour collection and analysis of odour intensity

The collected pads were placed in a polypropylene container with a lid and a ϕ15 mm hole (online supplemental figure 2), and 3000 mL of air was aspirated through the hole via an odour adsorption tube containing 2,6 diphenyl-p-phenylene oxide polymer (Tenax TA 60/80, GERSTEL & Co. KG, Germany).

The collected odour was analysed using 6890N/5975B inert XL MSD (Agilent, Santa Clara), a gas chromatography-mass spectrometry (GC-MS) system, which was coupled to a thermal desorption system (GERSTEL & Co. KG). The DB-WAX GC column was 60 m long×0.25 mm (J&W Pharmlab, Pennsylvania, USA). The odour components were

quantified using a calibration curve prepared in advance for the sum of the five odour components.

Questionnaire

Participants completed a questionnaire in both tests to document pad changes, reasons for changing, times of odour disturbance and satisfaction levels (rated 0–10). They also provided feedback on pad thickness, softness and any odour leakage. Medical staff were interviewed regarding the treatment of ulcerating cancer, pad application, and satisfaction with management methods, also rated on a 10-point scale.

Statistical methods

Statistical analysis used the χ^2 test to evaluate patient characteristics, with significance set at $p<0.05$.

RESULTS

The present study included 14 patients taking test A and 9 patients taking test B who subsequently gave their consent to participate. The median age was 67 years. The cohort included 13 females and 1 male. Ulceration causes were primary skin invasion in 10 patients and skin metastasis in 4 patients. Eight patients had LABC at diagnosis, with a median 12-month period from symptom onset to diagnosis. In six patients, ulceration developed during treatment. Breast cancer subtypes were luminal (n=11), HER2-positive (n=2) and triple-negative (n=1). Distant metastases included bone (n=4), lung (n=2), liver (n=4) and skin (n=5). Four patients underwent surgery and two received radiation therapy (online supplemental table 1).

Patients with LABC often experience exudation. In the present study, the largest quantity of exudate measured was 110 g/day, and the median quantity per sheet was 20 g. Local symptoms included exudation and ulceration in all the patients with odour, erythema, bleeding, itching and rash present in 10, 5, 4, 3 and 3 patients, respectively (online supplemental figure 2). Pad replacement frequency was once daily for seven patients and twice daily for another seven (online supplemental table 2). Ulcer treatments included gauze (n=8), wound pads (n=3), urinary pads (n=1), sanitary napkins (n=1) and the Hakujuji Moiskin pad (n=1). Petroleum jelly, Lozex and Mors Ointment were used by seven, five and one patient, respectively.

Odour evaluations showed that 9 of 14 patients in test A experienced significantly better improvement with the Komagome Pad compared with conventional pads (figure 1B; paired t-test: $p<0.01$). Assessment of odour intensity using GS-MS found the odour level with the Komagome Pad to be lower than with the conventional pad (figure 1C; paired t-test: $p=0.02$).

On the patient questionnaire, Komagome Pad was reported to be large and stable (n=4) or had a deodourising effect (n=2) while some found it too large (n=3). The patients' satisfaction level found no significant difference between the groups (figure 1D). The satisfaction levels within the high-exudation group (>20 g exudate) found that the Komagome Pad was associated with a significantly higher (figure 1E; $p=0.04$).

Test B assessed the long-term safety of the Komagome Pad over 1 month, with no adverse events reported by the nine patients, confirming its safety.

Overall, the study suggests that the Komagome Pad effectively manages odour and exudation in LABC patients, particularly those with high exudation levels and is safe for long-term use.

DISCUSSION

Ulcerating cancer can be treated by addressing the primary disease and managing local symptoms. Primary treatments include surgery, drug therapy and radiation therapy. Surgery may alleviate symptoms, but it is often challenging for advanced lesions. Such lesions are rarely life-threatening unless accompanied by large metastatic lesions in vital organs, necessitating long-term treatment. The study noted a median time of 1 year from symptom onset to diagnosis, indicating prolonged suffering and impaired quality of life for patients with LABC. Only two patients saw improvement in their local lesions postresection. Drug therapy can temporarily shrink tumours and relieve symptoms, though these usually recur as the treatment loses effectiveness. Radiation therapy also offers temporary symptom relief, but the disease often spreads to the surrounding tissue with the passage of time.

Local symptom management typically involves using occlusive materials like gauze and ointments. The amount of gauze is determined by the level of exudation, sometimes supplemented with absorbent pads. Patients commonly use commercial products such as gauze, pads, deodorant sheets and even pet and sanitary products due to the lack of specialised items for patients with breast cancer. Petroleum jelly prevents the adhesion of the gauze to the tissue and bleeding. Metronidazole ointment prevents bacterial growth and was now replaced by Rosex Ointment, which is now frequently used.[5–7] Mohs' ointment is prepared to prevent bleeding . However, both ointments only relieve the symptoms, and their application is time-consuming.

This study had limitations, including a small sample size, short observation period and qualitative odour evaluation without a double-blind approach. Nonetheless, the Kao Odour Panel and GC-MS confirmed the Komagome Pad's effectiveness in odour suppression. The promising results have led to plans for future clinical trials and multicentre studies to further investigate the pad's efficacy.

Contributors All authors contributed to the study conception and design. Komagome Pad was developed by HI. MI, YT, MS, YF, HK, TK and TI. Material preparation, treatment of LABC and data collection were performed by SI, MN, CS. NI, RG, TA and TI, HI and YT did the odour evaluation by sensory

testing. HI and YT evaluated the odour intensity by GC-MS. The first draft of the manuscript was written by TI and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests HI, MI, YT and MS are permanent employees of Kao Corporation. Other authors have no conflict of interest with this article. Kao Corporation was involved in the preparation of this article in terms of odour collection, analysis and statistical interpretation of the data.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval The study adhered to ethical guidelines outlined by the Ethics Committee of Tokyo Metropolitan Cancer and Infectious Diseases Center, Komagome Hospital and the Declaration of Helsinki for research involving human subjects. Approval was obtained from the Internal Review Boards of both Komagome Hospital and Kao Corporation.

Provenance and peer review Not commissioned; externally peer reviewed.

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