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SHOULDER

Cold versus cold compression therapy after shoulder arthroscopy: a prospective randomized clinical trial

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Abstract
Purpose Purpose of the present study was to investigate the acute effects of a cold compression bandage on pain, swelling and skin-surface temperature after the first 24 h after arthroscopic surgery of the shoulder in a stationary setting and to compare it with cold therapy using only a cold pack. It was hypothesized that using the bandage is more effective in reducing pain and swelling after 24 h compared with using only a cold pack.
Methods Fifty-two patients (53 ± 12.2 years) were randomly assigned to two groups after arthroscopic surgery. The first group wore a cold compression bandage, and the second group a conventional frozen cold pack. Pain, swelling and skin-surface temperature were measured 2, 8 and 24 h after surgery. Differences within and between groups were analysed.
Results Both groups showed a significant reduction of the circumference of the arm 15 and 20 cm proximal of the lateral epicondyle 24 h after surgery (cold compression: $p = 0.003$; $p < 0.001$; cold: $p < 0.001$). Pain at rest was significantly reduced with cold compression bandage 24 h after surgery ($p = 0.001$). Skin temperature increased in both groups 24 h after surgery (bandage: $p < 0.001$; cold pack: $p = 0.002$). After 24 h, pain during activity was significantly decreased in the group wearing the bandage compared with the group using the cold pack ($p = 0.026$).
Conclusions Based on the results of this study, no recommendation can be made with respect to the question whether cold compression therapy or cold therapy should be preferred immediately after arthroscopic surgery of the shoulder. Clinicians should question the need of expensive cold compression bandages in the short-term post-operative treatment after arthroscopic surgery of the shoulder.
Level of evidence II.

Keywords Arthroscopic surgery · Cold compression therapy · Comparison · Bandage · Pain · Swelling

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Introduction

Following surgery and injury, cooling of the operated or injured area has an analgesic effect [6]. However, cold therapy or cold compression therapy is used with controversial results. Reduced pain [12, 20, 21, 25], blood loss [14, 25], swelling [20] and administration of analgetics [7, 14, 25], increased range of motion [7, 14], improved function and shortened hospital stay [12] were reported with the use of different cold and cold compression devices. Thereby, particularly compression reduces blood flow and the development of oedema [17]. Furthermore, it decreases haemarthrosis [12] and protects soft tissues [2, 12]. However, there are studies that showed no benefits of cold compression therapy compared with only cold therapy [9, 22]. In most of these studies, the knee was investigated [7, 9, 12, 14, 20, 25]. Only two studies explored cold compression therapy after open or arthroscopic surgery of the shoulder [21, 23].

Thus, the benefit of the use of compression combined with application of cold after shoulder surgery is currently not clarified. Furthermore, different cooling methods, such as ice packs, cold water immersion or ice massage were suspected to differ in their effectiveness for reducing skin temperature, nerve conduction velocity and thus in their analgesic effects [10]. It is essential to explore which method is most effective in reducing pain after surgery and, as previously stated, whether there is a need to investigate the effect of new cold therapy devices and to compare them with conventional ice application methods [16], especially after shoulder surgery.

A new bandage for the shoulder (Darco Arctic Air® Shoulder) was designed for cold compression therapy using exchangeable cold packs and a pump system for applying compression on the shoulder. Therefore, the purpose of this study was to elucidate whether a treatment using this bandage would reveal an acute beneficial effect with respect to pain, swelling and skin temperature of the shoulder compared with cold therapy using only a cold pack. It was hypothesized that patients using the cold compression bandage develop less pain and less swelling after 24 h compared with the patients using only the cold pack.

Materials and methods

For this prospective randomized clinical study with two groups, patients, who were scheduled for arthroscopy of the glenohumeral joint, were recruited from the orthopaedic consultation at the Orthopaedic Department of the University Hospital Münster. They were randomly assigned to an experimental group (cold compression bandage) and a control group (cold pack) without compression using a computerized block randomization with blocks of 4 and a concealed allocation using closed envelopes (Fig. 1).

Inclusion and exclusion criteria

Inclusion criteria for the study were indications for arthroscopic surgery of glenohumeral joint structures. Patients with contraindications for cold therapy, like peripheral vascular or cardiovascular disease, diabetes, neurological or skeletal muscle disorders, local hot or cold insensitivity, hypersensitivity or allergy, cold adverse reactions as well as Raynaud and Buerger disease were excluded [10, 16]. After informing the patients about the aims and procedures of the study, a written informed consent was obtained.

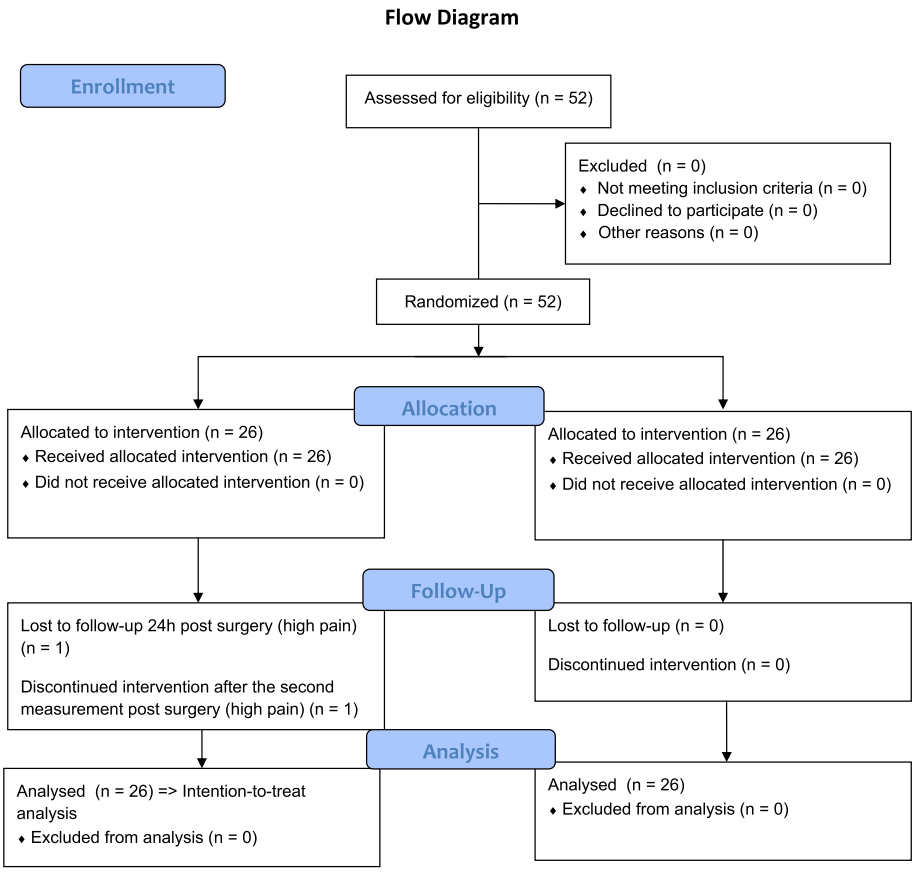

Fig. 1 Flow chart

Arthroscopic surgery

All included patients were scheduled for arthroscopic shoulder surgery by the same fellowship-trained shoulder surgeon. All procedures were performed in beach-chair position. The forearm was placed in a holding device to ensure that the arm remained stable. A slight traction was applied to the arm. Inclusion criteria were an American Society of Anesthesiologists (ASA) physical status of I to III and an age between 18 and 75 years. All surgical procedures were carried out arthroscopically and included subacromial decompressions, rotator cuff repairs, calcific deposit removal and Bankart repairs. All surgeries were performed under general anaesthesia induced by the injection of propofol (2 mg/kg), sufentanil (0.2 µg/kg) and cisatracurium (0.1 mg/kg) and maintained by the inhalation of sevoflurane (0.8 MAC) and the supplementation of sufentanil according to clinical criteria.

Cold compression therapy

The Darco Arctic Air® Shoulder (Darco Europe GmbH, Raisting, Germany) is a commercially available bandage for cold compression therapy of the shoulder. As suggested by the manufacturer, it can be used for post-traumatic and post-operative care. The bandage can be applied at the right as well as the left shoulder. Before applying the bandage directly after arthroscopy, the pump system was connected with a valve at the bandage. A cold pack (Arctic Air® Instant Cold Pack, Darco Europe GmbH, Raisting, Germany) was activated by breaking and shaking it and then fixed with Velcro® dots inside the bandage. Temperature in the first 30 min of cooling is supposed to range from 3 to 8 °C. At each measurement after surgery, the cold pack was replaced by a new cold pack (Arctic Air® Cold Pack, Darco Europe GmbH, Raisting, Germany) which was stored in the refrigerator within an enclosed plastic bag at a temperature of 3 °C. Risk of damage to the skin could be excluded because time periods between changing the cold packs were long and temperature of cold packs increased over time. Furthermore, temperatures above 4 °C are perceived as comfortable by patients [6]. The bandage was fixed at the shoulder with Velcro® straps around the upper arm and the thorax while the patient was lying in supine position. For compression, air was hand-pumped into the bandage with the enclosed pump system until the bandage was tightly filled.

Cold therapy

For cold therapy, a common cold pack that was stored in an ice box was used. The cold pack was covered with a cloth to protect the skin from potential thermal damaging. Patients were instructed to apply the cold pack for 15–20 min per hour and to remove it when they felt any discomfort. Nurses supervised the cooling process and changed cold packs hourly. No loss of protective sensation and pain was present at the time after surgery because patients received general anaesthesia and not an interscalene nerve block. So the risk of thermal damaging related to loss of sensation and pain could be excluded. The surgeons were blinded to the type of intervention that was applied to the patients at every phase of the study.

Baseline and outcome measures

Baseline measures and informed consent were taken the day before surgery when the patient checked in the hospital. Outcome measures were taken 2, 8 and 24 h after surgery in the patient's hospital room. Primary outcome measures were pain at rest and during activities, i.e. dressing or during transfer from lying to sitting. They were determined using the visual analogue scale (VAS) where 0 represents no pain and 10 the highest imaginable pain. Secondary outcome measure was the circumference of the upper arm. It was measured at two points using a tape measure: (1) insertion of the deltoid muscle at the level of the deltoid tuberosity, 15 cm above the lateral epicondyle; (2) 20 cm above the lateral epicondyle. Pain intensity measured with a VAS and the extent of oedema determined with circumference measurements are considered as primary outcome measures in studies investigating the effectiveness of cryotherapy after arthroscopic surgeries [15] with almost high reliability (pain intensity: $r = 0.73$–0.82; circumferential measurements: ICC = 0.97–0.99) and validity (pain intensity: $r = 0.65$–0.92; circumferential measurements: $r = 0.98$) [5, 8, 24]. Skin temperature was measured using an infrared thermometer (Trotec Temp Tection BodyPlus Infrared Thermometer; Trotec GmbH & Co. KG, Heinsberg, Nordrhein-Westfalen, Germany) at three points:

- beside the dorsal arthroscopic access, 1–2 cm medial of the lateral edge of the acromion and 1–2 cm caudal of the dorsolateral acromion
- beside the lateral subacromial access, 1–2 cm below the edge of the acromion
- beside the anterior-inferior access, 1 cm lateral of the coracoid process.

The thermometer measures surface temperature accurately in a distance from 5 to 15 cm with a deviation of 0.3 °C as reported by the manufacturer. All points for measuring circumference and skin temperature were marked with a waterproof pen to ensure measuring the same points before and after surgery. Infrared surface thermometry was previously reported to show high

Table 1 Differences of outcome measures within and between the group "cold compression therapy" using the bandage (Darco Arctic Air Shoulder) and the group "cold therapy" using the cold pack

Outcome measures	Darco Arctic Air Shoulder			Cold pack			Differences between groups
	Mean	SD	Friedman *p*-level	Mean	SD	Friedman *p*-level	Mann–Whitney *U* test *p*-level
Circumf 15 lat pre	32.4	3.1	<0.001	34.0	4.1	<0.001	n.s.
Circumf 15 lat 2 h post	33.5	3.4		35.3	4.6		
Circumf 15 lat 8 h post	33.1	3.3		35.0	4.4		
Circumf 15 lat 24 h post	32.6	3.2		34.3	4.5		
Circumf 20 lat pre	34.5	3.4	<0.001	36.0	4.2	<0.001	n.s.
Circumf 20 lat 2 h post	36.0	3.6		37.8	4.8		
Circumf 20 lat 8 h post	35.5	3.5		37.0	4.5		
Circumf 20 lat 24 h post	34.4	3.6		36.2	4.6		
VAS_rest pre	2.9	2.8	n.s.	2.7	2.9	n.s.	n.s.
VAS_rest 2 h post	3.9	2.4		3.0	2.5		
VAS_rest 8 h post	2.7	2.0		3.0	2.5		
VAS_rest 24 h post	2.3	1.8		2.4	2.2		
VAS_activ pre	5.6	3.1	n.s.	6.5	2.8	0.0119	n.s.
VAS_activ 2 h post	5.5	2.8		5.6	2.6		
VAS_activ 8 h post	5.6	2.6		6.3	2.3		
VAS_activ 24 h post	5.1	2.4		6.5	2.2		0.026
T_skin pos pre	32.8	1.6	<0.001	32.4	2.5	0.0296	n.s.
T_skin pos 2 h post	30.0	2.4		32.0	2.3		0.002
T_skin pos 8 h post	33.4	1.7		32.0	4.4		n.s.
T_skin pos 24 h post	33.7	3.1		34.0	1.4		
T_skin lat pre	33.0	1.3	<0.001	32.6	1.5	<0.001	n.s.
T_skin lat 2 h post	30.4	2.9		30.6	3.7		
T_skin lat 8 h post	33.0	1.8		31.9	3.1		
T_skin lat 24 h post	33.8	2.1		34.5	1.5		0.046
T_skin ant pre	33.6	1.7	<0.001	33.6	1.6	<0.001	n.s.
T_skin ant 2 h post	31.7	1.9		31.8	1.9		
T_skin ant 8 h post	33.8	1.4		32.4	3.1		
T_skin ant 24 h post	33.8	2.3		34.4	1.6		

Circumf 15 lat, circumference 15 cm proximal of the lateral epicondyle; Circumf 20 lat, circumference 20 cm proximal of the lateral epicondyle; VAS_rest, pain (visual analogue scale) at rest; VAS_activ, pain (visual analogue scale) during activity; T_skin pos, skin temperature at posterior access; T_skin lat, skin temperature at lateral access; T_skin ant, skin temperature at anterior access

validity ($r = 0.92$–0.98) and reliability ($r = 0.97$) and is therefore recommended for measuring skin temperature [3, 4]. Room temperature and body temperature were controlled at all times of measurements to avoid differences that could have influenced skin temperature measurements within and between groups. Each patient was operated under the same conditions, e.g. with the same room temperature. As patients were not warmed during surgery, no unwanted increase of body temperature could have influenced the outcome measures. After surgery, patients were treated with a standardized pain protocol including non-steroidal anti-inflammatory agent (paracetamol/novalgin) as well as a pain medication (valoron) if necessary.

Institutional review board approval for the study was provided by the "Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms-Universität Münster" (AZ: 2011-335-f-S). Financial and material support was provided by Darco (Europe) GmbH.

Statistical analysis

Sample size estimation indicated a necessary number of 26 patients per group in order to detect a clinically relevant difference of 2 points on the visual analogue scale (effect size $d = 0.8$) between the groups with a probability of $1 - \beta = 0.8$ at a significance level of $\alpha = 0.05$. Means and

standard deviations were calculated for both groups. The Kolmogorov–Smirnov test and histograms indicated a non-parametric data distribution. Significance of differences of outcome measures over time was tested using Friedman tests. For pairwise comparisons, the Wilcoxon signed-rank test with appropriate Bonferroni correction was used ($p < 0.05/6$). Significance of differences of outcome measures between groups was tested using the Mann–Whitney U test ($p < 0.05$). An intention-to-treat analysis was performed, with patients analysed in the group to which they were allocated. For dropouts, missing data were replaced with the mean score of the respective group for each missing value of the respective outcome parameter. Statistical tests were performed using IBM SPSS® Statistics 21 for Windows (IBM Corporation, Somers, NY, USA).

Results

Fifty-two patients (21 female, 31 male) with a mean age of 53 years and a standard deviation (SD) of ±12.2 years volunteered to participate in the study. Both groups were comparable with respect to age, gender, height, body mass, subjective pain, circumferences of the upper arm and skin temperatures (n.s.). Body temperature ranged from a mean of 35.9 °C to 36.2 °C in both groups showing no differences within and between groups (n.s.). Room temperature ranged from a mean of 22.3 to 22.5 °C in the cold compression therapy group and from a mean of 22.3 to 22.6 °C in the cold therapy group with no differences within and between groups (n.s.). A total of 34 right shoulders and 18 left shoulders were measured before and after arthroscopic surgery. Fifty-one patients completed treatment. One patient dropped out after the second measurement after surgery because he experienced high pain.

There were significant differences in skin temperature at the dorsal, lateral and anterior-inferior access over time for the cold compression therapy group ($p < 0.001$) (Table 1). Significance of pairwise comparisons of outcome measures pain at rest as well as circumference of the proximal humerus is illustrated in Figs. 2 and 3. Furthermore, significantly lower pain levels during activity at 24 h after surgery for the cold compression therapy group compared with the cold therapy group ($p = 0.026$) were found (Fig. 4). No further differences were observed between groups.

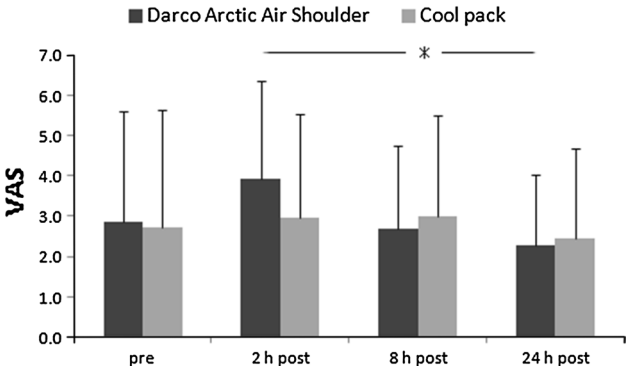

Fig. 2 Significance of differences within groups of pain at rest rated on the visual analogue scale (cm). Wilcoxon signed-rank test, $^*p = 0.001$

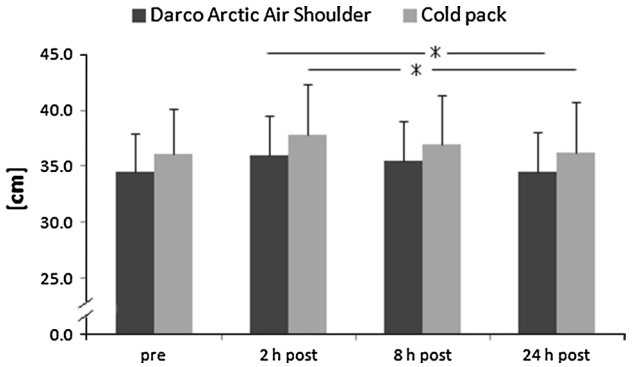

Fig. 3 Significance of differences within groups of circumference 20 cm above the lateral epicondyle. Wilcoxon signed-rank test, $^*p < 0.001$

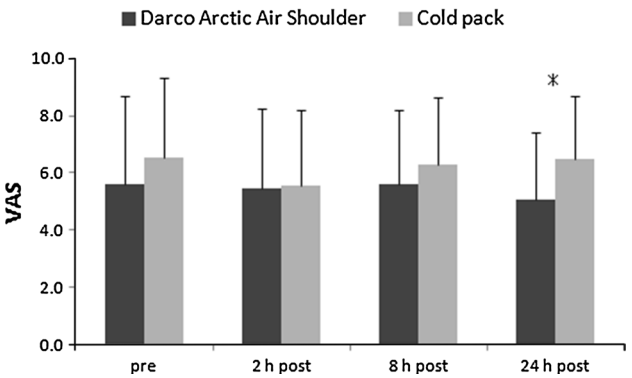

Fig. 4 Significance of differences between groups of pain during activity rated on the visual analogue scale (cm). Mann–Whitney U test, $^*p = 0.026$

Discussion

The most important finding of the study was that cold compression therapy using a bandage (Darco Arctic Air® Shoulder) demonstrated no beneficial effect on pain at rest and swelling, represented by the circumference of the upper arm, when compared with only cold therapy in patients who underwent shoulder arthroscopy. Therefore, the hypothesis that patients applying cold compression bandages develop less pain and less swelling after

24 h compared with patients using only cold packs has to be rejected. These results might have been caused by an insufficient compression due to an inadequate enclosure of the shoulder by the bandage. However, as no information exists about the actual pressure applied on the shoulder tissues, this assumption cannot be substantiated. The bandage seems to provide a protection and support for the shoulder during activities. This could be seen in the lower pain level during activity 24 h after surgery in the cold compression group. Both interventions reduced pain at rest and swelling from 2 to 24 h after surgery and kept these symptoms under control. These results underline that cryotherapy provides beneficial effects during post-operative care such as reducing severity and frequency of pain [19, 21, 23]. As shown in the ankle and calf region, reduced pain might be explained by increasing the pain threshold which is considered to be associated with a decreased nerve conduction velocity [1, 10].

Skin temperature measurements, although taken by infrared thermometry at skin surface, showed comparable results with previously reported measurements inside the glenohumeral and subacromial spaces (31–34 °C before and 35 °C post shoulder arthroscopy) using temperature probes [13]. In accordance with the results of Okcu et al. [18], skin temperature decreased significantly with and without bandage 2 h after surgery. However, this decrease was considerably less pronounced. Furthermore, in the present study, 24 h after surgery, skin temperature increased compared with baseline measurements. A reason might be the inflammatory tissue reaction. Okcu et al. [18] investigated skin temperatures after ice application (−15 °C) under casts around the ankle which might have led to the differing results, because casts might embrace the ankle joint more tightly compared with the shoulder. In the present study, temperature in the bandage condition was between 3 and 8 °C, and in the cold pack condition, the cold pack was not fixed, so that patients were able to move it when they felt uncomfortable. Osbahr et al. [19] reported skin-surface temperatures of about 33 °C 8 h and about 34.5 °C between 12 and 23 h after open rotator cuff repair in the shoulder for the group using a cryotherapy system where ice and water continuously circulated through a pad that was applied to the shoulder. Control subjects showed significantly higher temperatures of about 36.5 °C 8 h and 36 °C 23 h after surgery. In the present study, core body temperature ranged between 35.9 and 36.2 °C in both groups and was comparable to previously reported results [11, 19].

It has to be considered that no additional control group without cold or cold compression therapy was included in the study. Therefore, the benefits of cooling methods compared with no intervention are still not fully understood. However, this topic has to be clarified elsewhere, because the aim of this study was to explore additional effects of a cold compression bandage compared with only cold therapy. Furthermore, patients were treated with a standardized protocol of medication so that the effects of cold and cold compression therapy over time have to be interpreted with caution. It is not known how pain, swelling and temperature developed during the days and weeks after arthroscopy, so that the long-term effects of cold compression therapy compared with cold therapy is still not fully understood as well. Healy et al. [9] did not find a beneficial effect of cold compression therapy compared to cold therapy after 7 and 14 days as well as 6 weeks after total knee arthroplasty. Contrary to these results, Speer [23] reported that patients who received cold therapy reported less severity and frequency of pain 1 and 10 days after different surgical procedures of the shoulder compared to those without cryotherapy. As the investigation of long-term effects of the therapy interventions was not the aim of the present study, it has to be discussed and clarified elsewhere. In this study, different indications for arthroscopic surgery of the shoulder were included. Thus, potential differences of subjective pain and swelling regarding the treated tissue could not be controlled. However, the surgical indications in the two groups were similar. Another limitation might be that cooling protocols between both groups differed because of specific usage of the bandage. However, for cold compression therapy, studying the effectiveness of compression was the main subject of interest and therefore justified the minor difference between protocols.

As no clinically relevant benefit was found in this study for using a cold compression bandage, clinicians should question the need of expensive cold compression bandages in the short-term post-operative treatment after arthroscopic surgery of the shoulder.

Conclusions

Based on the results of this study, no recommendation can be made with respect to the question whether cold compression therapy or cold therapy after arthroscopic surgery of the shoulder should be preferred. Future research should investigate the application of the bandage after other, i.e. more severe or invasive shoulder surgery over a longer period of time.

Conflict of interest Financial and material support of the study was provided by Darco (Europe) GmbH.

Ethical standard "Ethik-Kommission der Ärtzekammer Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms-Universität Münster" (AZ 2011-335-f-S).

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