Management of leg and pressure ulcer in hospitalized patients: direct costs are lower than expected

Behandlung des U. cruris und U. decubitus bei hospitalisierten Patienten: die direkten Behandlungskosten sind geringer als erwartet

Abstract

**Background:** In Germany, cost calculations on the financial burden of wound treatment are scarce. Studies for attributable costs in hospitalized patients estimate for pressure ulcer additional costs of € 6,135.50 per patient, a calculation based on the assumption that pressure ulcers will lead to prolonged hospitalization averaging 2 months. The scant data available in this field prompted us to conduct a prospective economical study assessing the direct costs of treatment of chronic ulcers in hospitalized patients.

**Study design:** The study was designed and conducted as an observational, prospective, multi-centre economical study over a period of 8 months in three community hospitals in Germany.

**Patients:** Direct treatment costs for leg ulcer (n=77) and pressure ulcer (n=35) were determined observing 67 patients (average age: 75±12 years). 109 treatments representing 111 in-ward admissions and 62 outpatient visits were observed. During a total of 3,331 hospitalized and 867 outpatient wound therapies, 4,198 wound dressing changes were documented.

**Main outcome measure:** Costs of material were calculated on a per item base. Direct costs of care and treatment, including materials used, surgical interventions, and personnel costs were determined.

**Results:** An average of € 1,342 per patient (€ 48/d) was spent for treatment of leg ulcer (staff costs € 581, consumables € 458, surgical procedures € 189, and diagnostic procedures € 114). On average, each wound dressing change caused additional costs of € 15. For pressure ulcer, € 991 per patient (€ 52/d) was spent on average (staff costs € 313, consumables € 618, and for surgical procedures € 60). Each wound dressing change resulted in additional costs of € 20 on average.

**Conclusion:** When direct costs of chronic wounds are calculated on a prospective case-by-case basis for a treatment period over 3 months, these costs are lower than estimated to date. While reduction in prevalence of chronic wounds along with optimised patient care will result in substantial cost saving, this saving might be lower than expected. Our results, however, do not serve as basis for making any conclusions on cost-benefit analysis for both, the affected individual, as well as for the society.

**Keywords:** costs chronic wounds, staff, consumables, surgical procedures, diagnostic procedures

Zusammenfassung

**Hintergrund:** In Deutschland gibt es nur wenige Daten zu den Behandlungskosten von Wunden. Schätzungen der zuordenbaren Behandlungskosten hospitalisierter Patienten für U. decubitus gehen von 6.135,50 € pro Patient aus, kalkuliert auf der Annahme, dass es durch das U. decubitus zu einer verlängerten Hospitalisierung von durchschnittlich 2 Monaten kommt. Die spärlich verfügbaren Daten haben uns veran-
lasst, eine prospektive ökonomische Studie zur Ermittlung der direkten Behandlungskosten für chronische Ulcera bei hospitalisierten Patienten durchzuführen.

**Studiendesign:** Die Studie wurde geplant und durchgeführt als prospektive multizentrische ökonomische Beobachtungsstudie für die Dauer von 6 Monaten in drei kommunalen deutschen Krankenhäusern.

**Patienten:** Die direkten Behandlungskosten für Beinulcera (n=77) und Decubitalulcera (n=35) wurden durch Beobachtung von 67 Patienten bestimmt (durchschnittliches Alter 75±12 Jahre). Insgesamt wurden 4.198 Wunden dokumentiert, davon 3.331 im Krankenhaus und 867 ambulant versorgt.

**Kalkulationsbasis:** Die Materialkosten wurden pro verwendete Einzelposition berechnet. Dazu wurden die Pflege- und Behandlungskosten einschließlich Kosten für chirurgische Interventionen und Personalkosten addiert.

**Ergebnisse:** Durchschnittlich ergaben sich für die Behandlung von Beinulcera 1.342 € pro Patient (48 €/d), davon Personalkosten 581 €, Verbrauchsmaterial 458 €, chirurgische Maßnahmen 189 € und Diagnostik 114 €. Jeder Verbandwechsel verursachte durchschnittlich 15 €. Für das U. decubitus ergaben sich durchschnittlich 991 € pro Patient (52 €/d), davon Personalkosten 313 €, Verbrauchsmaterial 618 € und chirurgische Maßnahmen 60 €. Jeder Verbandwechsel verursachte durchschnittlich 20 €.

**Schlussfolgerung:** Wenn die direkten Kosten für chronische Ulcera auf der Basis einer prospektiven Fall-bezogenen Analyse für eine Behandlungsdauer von drei Monaten berechnet werden, ergeben sich geringere Kosten als erwartet. Obwohl die Reduktion der Prävalenz chronischer Wunden durch optimierte Patientenpflege zu einer Kosteneinsparung führt, kann das Einsparpotential geringer ausfallen als erwartet. Unsere Ergebnisse erlauben keine Schlussfolgerung für eine Kosten-Nutzen-Analyse in Hinblick auf den betroffenen Patienten sowie die Gesellschaft.

**Schlüsselwörter:** Kosten chronischer Wunden, Personalkosten, Verbrauchsmaterialien, chirurgische Kosten, Diagnostikkosten

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**Background**

Shrinking reimbursement is forcing healthcare providers to evaluate the costs and quality of their practices. With the new Diagnosis Related Groups (DRGs) Payment System now taking effect in many European countries, it is critical for the viability of health care providers to cut costs in alignment with the reduced capitated rates. In this respect, providing wound care can be a financial risk because of intensive use of resources and poor clinical results that often persist despite many months of care. Therefore, the principle goals in wound management involve providing effective care while maintaining costs at a lower level. However, determining cost-effectiveness requires comparing the costs necessary to achieve a given clinical outcome, in this case, successful wound healing [1].

Because DRGs together with Prospective Payment System (PPS) were introduced by Medicare in the USA in 1984, valid cost analysis exists for the United States. It is estimated, that approximately 5 million U.S. wound patients generate annual costs for care in excess of $ 20 billion, growing 10% annually. Billions of dollars are spent every year on hospitalized wound repair patients [2]. Hospitals currently lose a tremendous amount of revenue as a result of the prolonged hospitalization of chronic wound care patients. The diagnosis-related groups for wound debridement and skin graft, skin graft with or without wound debridement for skin ulcers, and wound debridement for injuries are 30 days, 22.5 days, and 23.5 days, respectively [3]. These sometimes unnecessarily long stays place a huge burden on health care finance. The costs of successful wound repair can be anywhere from $ 75,000 to $ 90,000 with only partial reimbursement.

However, because DRGs were only recently introduced to the German health care system, cost calculations on the financial burden of wound treatment are still scarce and if available, are not comparable in the methods used [4]. Studies for attributable costs in hospitalized patients estimate for pressure ulcer grade 3./4. average additional costs of € 6,135.50 per patient [5]. However, this calculation is based on the assumption that a pressure ulcer will lead to a prolonged hospitalization averaging about 2 months. According to a consensus statement of the German Federation for Chronic Wounds (ICW), in 1997 it was estimated that 5.3 million West-Germans suffered from...
chronic venous insufficiencies and about 1 million had at least one leg ulcer [6]. It is estimated that 5% of patients hospitalized or cared for in rehabilitation clinics suffer from chronic wounds. Based on data from 1980/1981, it is estimated that in Germany € 1.3 billion are spent for leg ulcer each year [7]. However, these results are based solely on approximations of all-in-one payment by health care insurances without taking into account the costs of the used resources [8].

The prevalence of pressure ulcer is even higher. In Germany, a prevalence of 10–25% of pressure ulcer is estimated in ward patients, with rates of 30% seen in rehabilitation centres [9]. Based on expenses of insurance companies and social welfare system it is estimated that the total costs for care and treatment of pressure ulcer in Germany is between € 1 and € 2.3 billion. According to the ICW it is estimated that prophylaxis of pressure ulcer could reduce these expenses by € 384 million [6]. The scant data on this issue prompted us to conduct an observational, prospective economical study assessing the direct costs of treatment of chronic wounds in hospital patients in Germany.

**Methods**

The study was designed and conducted as a prospective, multi-centre economical study over a period of 8 months in three community hospitals in Bavaria, Germany. Patients were included into the prospective study starting from December 1st 1999 and ending July 31st 2000. Then, patients were followed for 3 months; hence, the last set of data was on January 31st 2001.

In order to obtain a representative cross section of different types of hospitals, one primary, one secondary and one tertiary care hospital was included to participate into the study. Hospital A, a primary care facility with 150 beds providing primarily medical services (general internal medicine, cardiology, rheumatology, psychosomatic and alternative treatment options) with additional special emphasis on rehabilitation. Hospital B is a secondary care 190 bed facility. Beside medical services also surgical and urological departments are provided together with an anesthesiology department. Hospital C is a 300 beds tertiary care center providing full medical and surgical services, anesthesiology, orthopedics, gynecology and obstetrics, ophthalmology and ENT. This hospital also provides vascular surgical services.

The detailed costs of treatment for chronic wounds were calculated prospectively for all patients admitted to hospitals who presented besides their primary diagnosis also an additional diagnosis of pressure ulcer or leg ulcer. For every patient with the diagnosis of pressure ulcer or leg ulcer a form sheet was filled out. It collected information about the patient’s name, date of birth, hospitals patient identification number, type, number, localization, and condition of the chronic wound. Also, patient’s history and related diagnostic procedures (i.e. angiography, MRI or performance of the ankle/brachial index) were collected.

Investigated chronic wounds included pressure ulcer (stage 2, 3, and 4) and leg ulcer, both, stasis and ischemic ulcers. Patients with co-morbid conditions were not excluded.

A second form sheet documented all used items and resources during each wound care session, which formed the basis of our cost calculation at all locations. All participating hospitals followed the recommendations published by the European Wound Management Association [10]. For each treatment day the hands-on time of staff together with all used equipment were noted and stratified between outpatient and on-ward treatment. The costs of equipment and consumables included the actual hospital’s buying price and any applicable discounts.

Surgical procedures were directly noted at the surgical department (material usage, hands-on time). Twenty-one surgical procedures were observed in total. All surgical procedures were performed only in hospital C. Hospital A and B referred their patients to hospital C. Hence, cost for surgical procedure for patients admitted to hospital A and B are based on hospital C costs. Personnel time was individually stratified by profession of health care workers and documented in minutes. After calculating the average income of health care workers per year, costs per minute were calculated. Facility maintenance costs and costs for emergency provision were not calculated, since only the direct attributable costs per wound treatment were studied. Costs for consumables were calculated on a per item base.

To assess success of the treatment healing or reduction in wound size was documented in parallel to the cost calculation. The condition of the wound was assessed during the first patient contact, and forwards the end of the treatment, with the maximum time point of assessment being 3 months after therapy. All wounds were documented for size along with the grade of the defect. The following grading scheme was used: grade 0: no ulcer, ulcer healed; grade 1: ulcer includes dermis; grade 2: ulcer includes subcutis; grade 3: ulcer includes fascia; grade 4: ulcer includes muscles; and grade 5: ulcer includes tendons, bones, and joints.

**Statistical Analysis**

All results were calculated using Epi-Info 2000 software package (Epi InfoTM 2000 version 3.3; Centers for Disease Control and Prevention, GA, Atlanta). Continuous variables were calculated as mean together with range (minimum and maximum values). Means were compared using the Wilcoxon rank sum test. Discrete variables were expressed as numbers (percentages) and compared using a two-sided chi-square test or Fisher’s exact test, as appropriate. All statistical tests were set at a power of 0.8 and alpha ≤0.05.
Table 1: Basic patient data and wound characteristics

|                | Leg ulcers | Decubitus ulcer | Total |
|----------------|------------|-----------------|-------|
| Number         | 77         | 35              | 112   |
| Patients age (years) | 73.9 ± 21 (33–94) | 76.9 ± 18 (39–95) | 75 ± 12 (33–95) |
| Duration of hospitalization (days) | 20 ± 7 (3–92) | 18 ± 9 (1–62) | 19 ± 5 (1–92) |
| Initial Size (cm²) | 49.8 ± 22 (1–690) | 16.2 ± 7 (1–90) | NA    |
| Size reduction (cm²) | 14.5 ± 10 | 11 ± 4 | NA    |
| Closure         | 18 (23.3%) | 5 (14.3%) | 23 (20.5%) |
| Improvement     | 47 (61.2%) | 8 (22.8%) | 55 (49.1%) |
| No improvement  | 8 (10.3%)  | 20 (57.1%) | 28 (25.0%) |
| Worsening       | 4 (5.2%)   | 2 (5.8%) | 6 (5.4%) |

NA – not applicable

Results

A total of 112 documented ulcer treatments (77 leg ulcers and 35 pressure ulcers) were included in the analysis. Since patients had multiple hospitalizations, we observed 111 therapies in the ward and 62 ambulant therapies resulting in 867 patient contacts. Eighty-four wounds derived from female patients (75%) and 28 from male patients (25%). Mean male patient age was 66.3±13 years (range: 33–85); mean female patient age was 77.7±16 years (range: 35–95). The mean hospitalization duration was 19±5 days, range 1–92 days (leg ulcer: mean 20±7 days, range 3–92 days; pressure ulcer: 18±9 days, range 1–62 days), which was directly attributable to further diagnostic or therapeutic procedures.

Wound characteristics

Leg ulcer: In 29 patients, the wound was located on the right leg, in 27 patients on the left leg, in 21 patients on both legs. The number of wounds ranged from 1 to 4 wounds per patient, mean 1.6±1 wounds. The initial mean size of wound was 49.8±22 cm² (range: 1 to 690 cm²). In 18 wounds, the wound healed completely (23.3%) and in 47 wounds (61.2%) the wound condition was improved. However, in 8 wounds (10.3%) no improvement could be achieved, while in 4 wounds (5.2%) the wound worsened. The wound size was minimized by a mean of 14.5±10 cm². There was no significant difference within the 3 observed hospitals (P=0.657).

Pressure ulcer: In 35 patients, 26 wounds were located at the sacrum, in 14 wounds on the feet, and in 13 wounds in the heels. The initial mean size of wound was 16.2±7 cm² (range: 1 to 90 cm²). The wound size could be minimized by 11±4 cm², which represented a mean reduction by 32%. Again, there was no significant difference (P=0.786) within the 3 observed hospitals. Details are summarised in Table 1.

Costs

The total observed patient-days were 1,729. For hospitalized patients, a total of 1,449 patient-days, and for outpatient patients a total of 638 visits were observed. A total of 3,331 hospitalized and 867 outpatient wound treatments were performed. Some wound dressings had to be changed more than once a day and often more than one wound was treated during the same session. Wound treatment involved registered nurses in 3,094 procedures, medical doctors in 556 procedures, and other healthcare professionals in 1,174 procedures. In most cases, wound dressing was changed by more than one person. Changing wound dressings required 75,860 minutes in total (nurses: 56,924 minutes, medical doctors 3,846 minutes, and medical helpers 15,090 minutes). For each change of wound dressing, a mean time of 13±7 minutes for nurses, 1±1 minute for medical doctors, and 3±2 minutes for medical helpers was noted. There was no significant difference between wound treatment of outpatients or hospitalized patients (P=0.759). For each change of wound dressing, mean staff costs was calculated to be € 7.73±4, while each change of wound dressing generated additional costs for consumables of € 8.44±6. Costs of consumables for outpatients (mean: € 4.22±2) were significantly lower than costs for hospitalized patients (mean: € 9.40±5). For each treatment costs for consumables for hospitalized patients were € 15.48±8 and € 16.90±10 for outpatients (Table 2).

Surgical procedures

For each surgical procedure total cost of € 504.94±137 was calculated, with consumable costs of € 207.83±87 (Table 3). When this amount was calculated per patient, a mean of € 6.77±3 had to be added for leg ulcer and € 3.14±2 for pressure ulcer. Thus, this amount has to be included in the total costs per patient or per treatment, respectively.

Additional diagnostic procedures

The additional diagnostic procedures for leg ulcer patients (mean: € 86.41±16) increased the cost on an average by € 3.35±2 per patient. For pressure ulcer, no additional diagnostic procedures were performed.
Table 2: Costs of material per change of wound dressing and per treatment day

| Hospital | Costs of on ward treatment per | Costs of outpatient treatment per |
|----------|--------------------------------|----------------------------------|
|          | a) change of wound dressing | a) change of wound dressing |
|          | b) treatment day | b) treatment days |
|          | mean ± SD | min. | max. | mean ± SD | min. | max. |
| A*       |          |      |      |          |      |      |
| a) € 6.85 ± 3 | € 0.87 | € 60.28 | – | – |
| b) € 14.16 ± 7 | € 1.74 | € 115.91 | – | – |
| B        |          |      |      |          |      |      |
| a) € 10.02 ± 5 | € 0.11 | € 73.63 | € 5.08 ± 3 | € 0.11 | € 32.52 |
| b) € 17.59 ± 9 | € 0.11 | € 235.91 | € 18.08 ± 11 | € 0.11 | € 34.51 |
| C        |          |      |      |          |      |      |
| a) € 9.42 ± 6 | € 0.05 | € 258.05 | € 3.09 ± 2 | € 0.12 | € 47.04 |
| b) € 15.35 ± 10 | € 0.12 | € 260.45 | € 13.84 ± 7 | € 0.12 | € 47.04 |
| Total    |          |      |      |          |      |      |
| a) € 9.40 ± 5 | € 0.05 | € 258.05 | – | – |
| b) € 15.48 ± 8 | € 0.11 | € 260.45 | – | – |

* in hospital A, no outpatients were treated

Table 3: Detailed costs for surgical procedures (only Hospital C)

| Total observed costs | Mean costs per operation ± SD |
|----------------------|-------------------------------|
| Anaesthetist         | € 1780.83                     | € 84.80 ± 9                  |
| Anaesthetic nurse    | € 1002.13                     | € 47.72 ± 6                  |
| Surgeon              | € 1290.09                     | € 61.43 ± 12                 |
| Surgical assistance  | € 769.34                      | € 38.27 ± 4                  |
| Scrub nurse          | € 803.75                      | € 36.63 ± 3                  |
| OR technician        | € 593.25                      | € 28.25 ± 5                  |
| Materials used       | € 4390.39                     | € 207.83 ± 87                |
| Total costs          | € 10603.71                    | € 504.94 ± 137               |

Total direct costs

When all separate costs are summed together, the mean total cost of € 48.04±13 per treatment or € 1,343.11 per patient was observed for leg ulcer, and € 52.15±14 per treatment or € 990.76 per patient for pressure ulcer for the initial 3 months of treatment.

Discussion

Treatment of chronic wounds is not only a medical challenge, but due to extensive usage of resources and their respective costs has also become a topic widely discussed in medical economic forums. In the USA and UK the economical aspects always have been evaluated, while in German speaking countries these issues are only recently gaining focus and only gross estimations exist. The aim of this study was to prospectively determine the true direct treatment costs chronic wounds over the period of 3 months treatment in clinical practice following European and national standards for the management of ulcer [10]. Resource use was added to centre specific costs to determine the direct treatment costs for each patient. However, indirect costs defined as productivity losses due to temporary or permanent work disability were not taken into account. Although also considered as part of direct costs, costs for running and maintenance of the hospital setting were not included. The reason for excluding these costs was the inability to identify costs for maintenance or energy supply down to the level of the individual user and patient. One solution would be modelling treatment and costs. In modelling, investigators make assumptions about which services are likely to be utilized differently, thus driving the difference in costs. However, measurement of resource use in practice has the advantage of measuring utilization that may not be anticipated by investigators. In either approach, there can be considerable debate about how to ascribe Euro (€) amounts to utilization counts.

Although a considerable effort for meticulous documentation was required, the calculation of costs for consumables was performed on the basis of the actual items and resources used, and measured in real practice. This procedure has also been proposed by Lang et al. 1994 [11], Schweitzer and Kuepper 1998 [12], and Schoeffski 2000 [13].

One exception in our study was the calculation of staff costs. For these costs, the known average income of health care workers stratified by speciality was used [14], [15]. This approach has also been recommended by others to allow controlling for differences in the salary structure [16]. For instance, if a patient who has been treated by a young, single nurse, this would have decreased the actual treatment expense and would result in underestimation of the costs associated with the use of human resources.

The importance of the cost of human resource has been demonstrated in several other studies. A retrospective analysis of the cost of pressure ulcer care in a long-term...
care facility showed that total nursing costs were three to ten times higher than the cost of consumables, regardless of ulcer severity [17]. When studying the cost of treating diabetic ulcer on an outpatient basis, Kantor and Margolis [18] found that the average cost of physician and physical therapy care was higher than the cost of the consumables needed to treat the ulcer. In a study on costs of consumables and nursing time needed in treating venous leg ulcers, “expensive” materials were actually less costly in overall management costs than dressings generally considered less expensive [19].

The design of our study differs to other studies, in which direct treatment costs were determined by multiplication of standard financial reimbursements with average time spent in hospital. Because standard financial reimbursements systems induce behaviour of maximization strategies, this method does not reflect the true direct costs of treatment and care. Moreover, standard financial reimbursements for certain clinical diagnosis also include investment shares, maintenance costs as well as possible shares for reserves and profits. Finally, usage of resources to treat associated co-morbidities are not subtracted from the true costs for treatment and care and will always lead to overestimation of true costs.

An example of how such a strategy will lead to overestimation of costs was published in 1995 [20]. In that study, patients with chronic wounds were identified retrospectively according to their discharge diagnosis regardless of underlying diseases. The average reimbursed expenses were € 245 per patient-day for the study population. This number was multiplied by the total of all patient-days and as a result, it was reported that therapy costs of patients with pressure ulcer average € 14,480. Another study [21] reported total costs for treating patients in German hospitals with more than 2.1 billion € per year. Dreessen and Schmidt [22] report the additional expense of pressure ulcer in hospitalized patients to be € 74 per day. They arrived at this amount by taking into account a longer hospital stay (assumption of 13 additional days on average) and multiplied these additional hospital days with a uniform reimbursement expense. Finally, it was reported that a patient with a pressure ulcer who is hospitalized will generate additional costs of € 6,228. However, these additional costs were mainly derived from the longer hospitalization, and it was not clear separated whether the prolonged length of stay was due to treatment of the ulcer or other underlying conditions.

Therefore, when costs of chronic wounds are calculated, it was recommended by Brooks et al. [23] or Javitz et al. [24] to calculate pure the costs directly associated with chronic wounds.

Following these considerations, we have calculated mean total direct treatment costs of € 48.04 per treatment or € 1,343.11 per patient for leg ulcer, and € 52.15 per treatment or € 990.76 per patient for pressure ulcer, respectively over the period of 3 months. In view of what was assumed until now for Germany, our results are surprisingly low. A recent study published by Narayanan et al. [25], however, report at least similar direct labour cost ranging between $ 51 and $ 62, which is not that far away from our results observed. However, if the previously discussed problems in cost calculation are taken into account, it becomes evident that hitherto published costs might have been overestimated. This observation could be of economical relevance. Currently, it is estimated that in Germany 1.5 million patients suffer from leg ulcer and 800,000 patients from pressure ulcer. Based on our findings of actually lower resource consumption and prolonged hospital stay (18 days for leg ulcer and 20 days for pressure ulcer), the total German per annum costs would be € 752 million for leg ulcer, and € 1.4 billion for pressure ulcer. These costs, although dramatically high, still are lower than was assumed until now and then the question arises, whether the cost saving-potential, which is assumed by health care officials, really exists in the expected magnitude. German health insurances estimated the saving potential for pressure ulcer in 1998 to be 50–75% of nearly € 2 billion spent each year, which would result in € 1 to 1.5 billion per annum saved extra capital. However, if our calculated direct treatment costs for pressure ulcer are closer to reality, then the potential for saving will be € 695 million to one billion. Relying on income generated by hypothetical savings today, which at the end might be lower than expected, will lead to new financial problems tomorrow.

However, since our data represent direct treatment costs only, and investigates the initial 3 months of treatment only, the final total true health care system costs attributable to the occurrence and care of pressure ulcers might be different. When discussing cost from a society’s perspective the direct treatment cost might be only a smaller fraction of the total cost to society and therefore the influence of reduced direct variable cost on the general burden of a disease might be negligible. Clearly, this matter needs further focused research, as funding the social health care system becomes more and more challenging in future.

Conclusion

When direct treatment costs of chronic wounds are calculated on a prospective case-by-case basis for a treatment period over 3 months, these costs are lower than estimated to date in Germany. While reduction in prevalence of chronic wounds along with optimised patient care will result in substantial cost saving, this saving might be lower than expected. However, since our study encompassed the initial 3 months of treatment only, our results do not serve as basis for making any conclusions on cost-benefit analysis for both, the affected individual, as well as for the society.

List of abbreviations

| DRG | Diagnosis Related Group |
| PPS | Prospective Payment System |
ICW – “Initiative Chronische Wunde”; German Federation for Chronic Wounds
MRI – Magnetic Resonance Imaging

Notes

Conflicts of interest

The authors have no financial or other conflict of interest to declare in relation to this manuscript and declare no financial or other relationships leading to a conflict of interest.

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Corresponding author:
Univ.-Prof. Dr. Ojan Assadian
Clinical Institute for Hospital Hygiene, Medical University of Vienna, Vienna General Hospital, Waehringer Guertel 18-20, 1090 Vienna, Austria, Tel.: +43-1-40400-1904; Fax: +43-1-40400-1907
ojan.assadian@meduniwien.ac.at

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