Incidence of pressure ulcer in patients using an alternating pressure mattress overlay: the ACTIVE study

Objective: The primary objective was to determine the clinical benefit of using a specific alternating-pressure mattress overlay (APMO) in the prevention of pressure ulcer (PU) in patients at medium to high risk.

Method: This prospective study was conducted in five rehabilitation centres and three nursing homes. Patients at medium to high risk of PU, but without PU at baseline, and lying between 15 and 20 hours per day on a specific APMO were included. The primary endpoint was the percentage of patients who developed a sacral, spine, heel or trochanteric PU (supine support areas) of at least category II, at day 35. All patients were included in the analysis.

Results: A total of 89 patients were included; of whom six patients (6.7%) dropped out of the study (average (±standard deviation) follow-up 32±5.4 days). No sacral, spine, heel or trochanteric PU of at least category II was reported (i.e., an incidence of 0% [95% Confidence Interval: 0–4.1%] according to the exact Clopper–Pearson method]. Patients were 'satisfied' or 'very satisfied' with the comfort and stability of the APMO. The caregivers assessed as 'very easy' or 'easy' the implementation, maintenance and use of the APMO (turning over, moving to a sitting position).

Conclusion: In combination with the usual measures to prevent PU, the results of our study showed a low incidence of PU in high-risk patients lying for between 15 and 20 hours a day on an APMO, use of which is therefore recommended in these patients.

Declaration of interest: SM received honoraria as coordinator of the study indirectly by Nukleus from Winncare France, France. CR and MM (working for Nukleus) also received indirect compensation from Winncare France. The study was sponsored and funded by Winncare France but it did not participate in the conduct of the study nor in the analysis of the data.

alternating-pressure mattress overlay • beds • life support system • pressure ulcer • prevention • wound • wound care • wound healing

A pressure ulcer (PU) (also called pressure injury, pressure sore or bedsore) is a localised injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear.[1,2]

The lesion may be in the form of intact skin or an open wound and may be painful. Ischaemia, stress, recovery of blood flow, tissue hypoxia and the pathological impact of pressure and shear pathological mechanisms interact in the development of PU. Soft tissue tolerance to pressure and shear forces can also be affected by microclimate, nutrition, tissue perfusion, comorbidities, and the condition of the skin and underlying tissue.[1]

The prevalence and burden of PU remain high,[3] and understanding of PU pathophysiology is progressing.[4,5]

PU prevention requires a global approach. It has been the subject of recommendations.[1,6–8] Among the measures to prevent PU in patients who are bedbound for a long time every day, it is recommended to reduce the duration of pressure and its intensity on the bone areas.[1] Several types of support surface designed to reduce the intensity and duration of pressure on contact points are available to caregivers in order to prevent PU. In 2018, the National Pressure Ulcer Advisory Panel Support Surface Standards Initiative[9] specified the foundational definition of a support surface: 'A specialized device for pressure redistribution designed for management of tissue loads, microclimate, and/or other therapeutic functions (e.g., any mattresses, integrated bed system, mattress replacement, overlay, or seat cushion, or seat cushion overlay).' The NPUAP has classified support surfaces as basic/standard hospital mattress and reactive support surface (non-powered or powered).[9]

The technical specifications of each support surface determine their expected performance in terms of PU prevention. For alternating-pressure air mattresses or mattress overlays, air cell thickness, flow and inflation/deflation cycle, and physical properties play a very important role in their effectiveness in terms of prevention.[10]

The present study aimed to determine the clinical benefit of using a specific alternating-pressure mattress overlay (APMO) in the prevention of pressure ulcer (PU)

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in patients at medium to high risk. The specific characteristics of the mattress are described in the method section.

The risk of PU was reduced by 69% in the alternating-pressure dynamic air mattress/mattress overlay groups versus standard mattress in the 2015 meta-analysis of McInnes et al.[10] (risk ratio (RR)=0.31; 95% confidence interval (CI): 0.17–0.58) including two trials. The risk of methodological bias was considered high. The difference between alternating-pressure devices versus constant low-pressure devices was not established.[10]

In a network meta-analysis, powered active air surfaces showed a statistical superiority in PU prevention in comparison with standard mattresses with an estimated RR of 0.42 (CI: 0.29–0.63) (moderate certainty of evidence) and with non-powered reactive foam surfaces with an estimated RR of 0.64 (CI: 0.42–0.96) (low certainty of evidence).[11] According to a recent systematic review, it is necessary to continue investigations to assess the use of support surfaces in the prevention of PU.[12]

The choice of surface support must be made according to each patient's level of risk of PU occurrence.[13,14] The use of each support surface must be adapted to the level of risk of PU occurrence and to the context.

The conditions for reimbursement by French national health insurance for support surfaces to assist in the prevention and treatment of PUs were specified in the 'Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé' (CNEDIMTS) opinion of December 2009.[15] The CNEDIMTS is an independent commission issuing opinions for health regulatory authorities in France. For alternating-pressure surface supports, manufacturers must provide evidence attesting to technical specifications and clinical data attesting to the performance of the support surface. Clinical data must follow the recommendations of the CNEDIMTS, appearing in Annex III to the opinion of December 2009.[15] According to the specifications of the mattresses or mattress overlay, indications for a prevention and adjuvant device in the treatment of PUs are precisely specified.

The main objective of this study was to determine the clinical benefit of using a specific APMO in the prevention of PU in patients at medium to high risk of PU.

Method

Design

This was a national, prospective, multicentre, observational, longitudinal study, with a patient monitoring/follow-up period of 35 days (±5 days). The study took place between June and December 2019 in five rehabilitation centres and in three nursing homes. Investigators were physicians specialised in physical medicine and rehabilitation, and neurologists or geriatricians qualified to take care of patients at risk of PU. The study was non-interventional and did not involve any risk or constraint in any of the procedures performed, and the products were used in the usual way, according to clinical guidelines.

The protocol follows the recommendations of the CNEDIMTS appearing in Annex III to the opinion of December 2009.[15]

Patients

Patients had to meet the following criteria to participate in the study: >18 years old; at medium to high risk of PU (clinical judgement and a score between 10–14 on the Braden scale[16] (six, maximum risk to 23, no risk); without PU on the day of inclusion; woken up during the day; lying between 15–20 hours per day on a specific APMO (but for <48 hours on this APMO); and weighing between 30–165kg. Patients (or their representative) should have been informed of the study and agreed to participate. In the event of the patient's inability to give consent, the patient's person of trust/legal representative could give consent for the patient to take part in the study. To fulfil CNEDIMTS requirements, patients with a life expectancy of <6 months or with malnutrition could not be included.

Malnutrition was defined for adults <70 years of age as weight loss ≥5% in one month or ≥10% in six months or a body mass index (BMI) ≤18.5kg/m^2 (excluding constitutional weakness); for adults ≥70 years of age, weight loss ≥5% in one month or ≥10% in six months or BMI ≤21kg/m^2 or the Mini Nutritional Assessment (MNA)[17] score ≤17 (/30) or albumin <35g/l.[18]

Course of study and data collection

When a patient fulfilled the participation criteria, the evaluating physician offered the possibility of participating in the study to the patient or to their representative, in the event of the patient's incapacity. If consent was given to participate, an information leaflet was given to the patient or their representative. A baseline visit was made, and the patient then continued to be monitored by the care team, which used the standard PU prevention measures, such as measures to decrease pressure (changing position, installation, use of supports), observing skin condition, maintaining skin hygiene, ensuring nutritional balance, promoting patient/caregiver participation in PU prevention and ensuring continuity of care.

Skin condition was monitored daily to detect the slightest appearance of a PU throughout the 35-day follow-up period. On day 35 (±5 days), a final visit was planned to record the occurrence of PUs during the study and their progression in the case of occurrence, and the secondary criteria of evaluation.

At baseline, the following information was recorded: patient demographics (age, sex, weight, height); place of patient care; condition responsible for the risk of PU; Braden score; comorbidities; previous mattress support surface (before installation of the specific APMO used in the study); skin condition—absence of current PU and history of PU; average time spent lying per day; bed installation; seated installation (equipment/support); physiotherapy; activity level of the patient; nursing protocol implemented (number of position changes per day; maximum time between two position changes; number of sheet changes per day, positions used).

At the end of the study (day 35 or before in the case of withdrawal), the occurrence of one or more PUs was recorded and, where applicable, their characteristics (location, size, worst category during the period, progression). The category was considered according to the NPUAP classification.[19] The following parameters were also recorded: patient's view on the comfort of the mattress (general comfort and stability); satisfaction of the nursing staff (ease of implementation, maintenance, use in terms of turnaround, in terms of moving the patient to a sitting position) (on a scale of 0–4); degree of moisture (humidity component of the Braden score); sound level of the mattress (on a scale of 0–4). If a patient had difficulty in responding on the comfort of the mattress because of their neurological state, the experience of the patient was recorded by the care staff in consultation with the patient's representative.

Technical incidents related to the mattress (such as breakdowns, valve problems) and adverse events (AE) were also recorded. An information log book (paper) was provided to patients and caregivers to collect any important clinical events.

The protocol specified that, in the event of premature discontinuation of the study of a patient, the patient should be evaluated in a similar way as on day 35.

Pressure-relieving support and measures to prevent PU

To be included in this observational study, patients had to lie for <48 hours on the APMO (Axtair Automorpho Plus, Winncare France, France). This APMO comprises an overlay, a foam support and a compressor, and is available in three bed widths (90cm, 100cm and 120cm).

The overlay comprises 18 independent and removable polyurethane ether cells with a 12cm height of therapeutic air, a head area with two static cells covered with a pillow, and four heel cells with independent discharge. The overlay is laid on a support base in polyether foam, >5cm thick, located in an independent compartment. A cardiopulmonary resuscitation (CPR) valve was added to permit a mattress deflation time of <20 seconds, assuming the need for emergency cardiopulmonary resuscitation. The device (overlay and base) is fully protected by a removable cover made of material impermeable to liquids but permeable to water vapour.

The main mode of action of the mattress is active. The air cells of the upper layer (overlay) are inflated and deflated regularly by the compressor. The compressor is based on a patented system of automatic and continuous calculation of the inflation pressure according to the patient's size. There are two other programmable operating modes available: static low-pressure mode, allowing the treatment of patients requiring transient immobilisation, and care mode, allowing the mattress overlay to be overinflated for up to 30 minutes to facilitate transfers or treatments. In practice, the use of these modes over the period of a day are short and intended for the actions of caregivers. Visual and audible alarms were available, and the operating manual was provided to patients and caregivers.

A previous study was carried out on 57 patients at medium or high risk of PU (Braden score ≤17, bedbound for >15 hours per day), free from PU at baseline in rehabilitation centres and using this specific APMO. Over a follow-up period of 31 days, a PU incidence of 7.0% (95% CI: 2.0–17.0) was highlighted.[20] All patients received PU prevention measures as personalised care protocols for each patient.

Outcomes

The primary endpoint was the percentage of patients who developed a sacral, spine, heel or trochanteric PU (supine support areas) between day 0 and day 35 or the end of the study. PU was defined as skin damage of at least stage/category 2 of the NPUAP classification.[19] Daily skin inspection made it possible to detect the occurrence of any PU over the follow-up period. Stage/category I PUs (persistent redness of the skin >24 hours) were not taken into account in the primary endpoint because they are difficult to diagnose with certainty (differential diagnosis problems) and because of large inter-individual variation in their assessment.[10]

The secondary end points were category I (all areas) PU incidence or PU incidence of any category in an area other than sacrum, heel, spine, heels and trochanteric; patient satisfaction with the comfort of the APMO; patient acceptance of the sound level of the APMO; and the care team's assessment of the use of the APMO and the moisture level. Safety was analysed by description of AEs and technical incidents.

Sample size

Assuming that 7% of patients developed a PU of at least category II of the sacrum, spine, heel and trochanteric between day 0 and day 35, 80 patients were needed to make it possible to demonstrate that the upper limit of the 95% CI of the percentage would be <20%, with a power of >95%. In view of the data in the literature,[21–26] a maximum upper bound of 20% appears to be clinically relevant.

Analysis of data

All the data from patients who agreed to participate in the study were taken into account, according to the general principle of intention-to-treat analysis.

No statistical test was carried out, the study being of a descriptive nature. Any missing data were extrapolated using the last observation carried forward technique. This meant that, in the event of premature termination of the study, the patient had to be evaluated and the data for the last day the patient was in the study was used as the data for day 35.

The 95% CI for the percentage of patients who developed a PU between inclusion and day 35 was calculated using the exact Clopper–Pearson method. Secondary endpoints are reported descriptively.

Ethical and regulatory approval

The project was submitted to an Ethics Committee (Personal Protection Committee Northwest I - Rouen

France No. 2019-A00798-49) and was approved May 2019.

Protection and confidentiality of patient data were guaranteed by compliance with applicable laws.

Results

Enrolment and baseline characteristics

A total of 89 patients were included in the study, of whom six (6.7%) dropped out of the study. Reasons include:

- Patient could not bear the inflation of the tubes (n=1)
- Patients presented a non-device-related AE (n=2, one patient with pulmonary congestion requiring hospitalisation on day 15, and one patient with an abscess on a scar following surgery on the cervical spine and requiring hospitalisation on day 14
- Patient needed a change of mattress on day 17 (problem of bed width for obesity) (n=1)
- Patient needed a change of mattress on day 21 (unknown reason) (n=1)
- Patient returned home (n=1).

The average time of follow-up (time between day zero and the last evaluation) was 32±5.4 (standard deviation, SD) days for the 89 patients. Patients (of whom 57.3% were male) were on average 73.1±20.5 years old and had an average BMI of 25.3±6.2kg/m^2. Demographic and clinical characteristics of patients at baseline are shown in Table 1. Of the patients, 38 (42.7%) stayed in five rehabilitation centres and 51 (57.3%) patients in three nursing homes. The average length of stay for patients was 2.6±3.7 years (n=89). Urinary incontinence was present in 85.4% of patients and anal incontinence in 68.5% of patients.

Patients included were at high risk of PU—mean score on the Braden scale was 12.8±1.6 at inclusion—with an average moisture score (on a scale of 0–4) of 2.2±0.8. Patients were lying down on average 16.6±1.8 hours/day. No patient had a PU at inclusion and 18 (20.2%) had a history of PU. The medical conditions responsible for the risk of PU were classified into: neurological (for example, hemiplegia, tetraplegia, stroke) for 44 (49.4%) patients; accidental (for example, fracture, trauma) for 25 (28.1%) patients; or multifactorial or of complex origin (such as cancer, older age) for 16 (17.9%) patients. In bed, 52 (58.4%) patients used cushions to prevent PUs, 18 (20.2%) patients used positioning materials and four (4.5%) patients used orthoses. When seated, 69 patients (77.5%) used a cushion to prevent PU.

Primary end point

No sacral, spine, heel or trochanteric PU of at least category II was reported (i.e., an incidence of 0%; 95% CI: 0–4.1%, according to the exact Clopper–Pearson method). The upper limit of the 95% CI was well below the 20% assumption and attests to the performance of the APMO.

Secondary end points: performance

A category I sacral PU occurred nine days after installation on the APMO in an 85-year-old female patient with dementia, with urinary and anal incontinence, a Braden score of 10 at baseline, and who was bedbound for 15 hours/day. The PU was still progressing at the end of the study on day 32 (no further data were available after this day) (without worsening). No PU in any other location was reported.

Patients were 'satisfied' or 'very satisfied' with the APMO in the majority of cases in terms of comfort (87.5%) and stability (77.3%) (Table 2).

The care team assessed as 'very easy' or 'easy' in the majority of cases the implementation (93.2%) and maintenance of the APMO (95.5%), and its use in terms of turning over (85.2%) and sitting position (88.6%) (Table 3).

Patients rated the sound level of the APMO as satisfactory or very satisfactory in the majority of cases (93.1%) (Table 2).

At day 35, the degree of moisture had not changed as compared to day 0. The moisture score was 2.2 (SD 0.8) on day 0 and 2.3 (SD 0.9) on day 35 on the moisture component of the Braden scale (ranging from 1 (constantly moist) to 4 (rarely moist)), and did not change between baseline and the end of the study.

Secondary endpoints: adverse events

In total, three AEs were reported in three patients, including two patients who stopped the study prematurely:

- An 85-year-old patient who developed a category I sacral PU nine days after installation on the study mattress
- A 46-year-old male patient, weighing 104kg and measuring 176cm, with quadriplegia of level C3 with left hemiplegia, bedbound 15 hours a day, prematurely released from the study for hospitalisation on day 15 due to pulmonary congestion. This event was considered a serious AE unrelated to the APMO. The patient did not develop PUs
- A 53-year-old male patient with accident-related mobility problems, bedbound 20 hours a day, weighing 60kg and measuring 170cm, hospitalised on day 14 for an abscess on a scar. This event was considered a serious AE unrelated to the APMO. The patient did not develop PUs.

Secondary endpoints: technical incidents

A technical incident was reported: in one case there was a difficulty in sliding the patient onto the shower stretcher, due to the mattress cover hanging over the mattress.

Discussion

The number of PUs observed during this study is very low, with an incidence of 0% (95% CI: 0–4.1% according to the exact Clopper–Pearson method) PUs in the included population. The upper limit of the 95% CI was well below the 20% assumption.

These results on PU incidence are similar to those observed in a similar study conducted in patients at risk of PUs and lying 10–15 hours per day on a similar

APMO.[26] The PU incidence observed in the MATCARP study was 1.2% (1/83).[26] Indirect comparisons should always be interpreted with caution because of the many confounding factors that can affect the results, such as the residence of the patients, their degree of disability, the course of disability (acute or chronic stage), PU prevention methods and evaluation methods.[27] Nevertheless, these results should be considered, bearing in mind the recent results of the very large PRESSURE^2 randomised clinical trial conducted in 2029 patients in 42 UK secondary/community facilities. The trial compared alternating-pressure mattresses (APMs) with high specification foam (HSF) for a maximum treatment phase of 60 days.[28] The primary outcome was time to developing a new PU category ≥II from randomisation to 30 days from the end of the treatment phase (maximum 90 days). The incidence of at least one new category II PU (7.9%) was not statistically significantly different between the two groups, with an absolute difference of 2% (APMs 70 PUs (6.9%), HSF 90 PUs (8.9%)). In a treatment phase sensitivity analysis (until day 90), 132 (6.5%) patients developed a new category II PU between randomisation and the end of treatment phase (APM 53 (5.2%), HSF 79 (7.8%)), with a statistically significant difference observed in time to development of category II PU in a Fine and Gray model (hazard ratio, HR=0.66 (95% CI: 0.46–0.93; exact p=0.0176)).[28]

The choice of patients included in the study was based on the criteria retained by the French authorities for this type of APMO (in this case, an alternating-pressure mattress or APMO comprising between 10–15cm of therapeutic air) to allow access to reimbursement, provided that the support device guarantees precise minimum technical specifications. The French authorities justify the exclusion of malnourished patients and patients with a life expectancy of <6 months to avoid the issue of people being lost to follow-up. The choice of patient profile at risk of PU by the French authorities in 2009 and corresponding to who should be treated with this type of APMO was largely based on expert advice. Indeed, the choice of a surface support adapted to the risk of the patient to prevent PUs remains a question that cannot be completely based on a high level of evidence.[13]

Table 1. Baseline characteristics of patients (full analysis set, n=89). Figures are mean±standard deviation (SD) unless specified

	Patients, n=89
Age, year	73.1±20.5
Male gender, n (%)	51 (57.3)
Body mass index, kg/m^2	25.3±6.2
Urinary incontinence, n (%)	76 (85.4)
Urinary incontinence (n=76), n (%)*	
Intermittent	23 (31.1)
Total	51 (68.9)
Anal incontinence, n (%)	61 (68.5)
Anal incontinence (n=61), n (%)	
Intermittent	15 (24.6)
Total	46 (75.4)
Braden score (6–23)	12.8±1.6
Hours in bed per day	16.6±1.8
Installation in bed, n (%)	
Use of cushions	52 (58.4)
Use of orthotics	4 (4.5)
Medical device for patient positioning	18 (20.2)
Number of changes of position per day (n=31)	5.2±1.4
Time between two changes of position (n=30), hours	4.0±1.2
Number of linen changes per day (n=32)	1.0±0.3
Using pressure-relieving cushions when seated, n (%)	69 (77.5)
Condition responsible for the risk of pressure ulcers, n (%)	
Injury	25 (28.1)
Multifactorial	16 (17.9)
Neurological	44 (49.4)
Other	20 (22.5)
History of pressure ulcers, n (%)	18 (20.2)

*Data on the nature of the urinary incontinence is missing for two patients

Limitations

This observational study presents certain weaknesses which attenuate the generalisation of the results. The non-comparative nature of the study alters the causality between the clinical outcome and the use of the APMO. Indeed, other preventive PU measures were used for each patient. These consisted of limiting the pressure time (change of position, installation), regularly observing skin condition, maintaining skin hygiene, ensuring nutritional balance, promoting the participation of the patient and their caregiver, and ensuring the continuity of care. The causality of the low incidence of PU observed in the study is therefore limited. Nevertheless, in view of the high risk level of occurrence of PU in the patients included, the use of this type of support surface appears to be suitable and it seems unlikely that the APMO has not contributed to PU prevention.

The duration of the study was only 35 days and may be considered too short. Even if it is established that a PU can appear in a few minutes or hours, a longer study period than 35 days could have shown a higher incidence. This period of >30 days is sufficient for the French authorities for this type of study, which is why we have chosen it.

Table 2. Patients' opinion on the comfort and sound level of the APMO at end of the study*

	General comfort n=88†	Stability n=88†	Sound level n=87‡
	n, (%)		
Not at all satisfactory	2 (2.3)	2 (2.3)	—
Not satisfactory	3 (3.4)	8 (9.1)	1 (1.2)
Neither satisfactory nor unsatisfactory	6 (6.8)	10 (11.4)	5 (5.8)
Satisfactory	51 (58.0)	44 (50.0)	21 (24.1)
Very satisfactory	26 (30.0)	24 (27.3)	60 (69.0)

APMO—alternating-pressure mattress overlay; *For 17 patients, due to neurological state, patient experience was recorded by the staff with subjective assessment by caregivers and/or patient representative(s); †one missing data; ‡two missing data

Table 3. Care teams' opinions on using the APMO, n=88*

	Set-up	Ease of cleaning	Ease of use in terms of patient turnaround	Ease of use in terms of lying to sitting
	n, (%)			
Not at all satisfactory	—	—	—	—
Not satisfactory	—	—	—	—
Neither satisfactory nor unsatisfactory	6 (6.8)	4 (4.6)	13 (14.8)	10 (11.4)
Satisfactory	26 (29.5)	25 (28.4)	55 (62.5)	31 (35.2)
Very satisfactory	56 (63.6)	59 (67.1)	20 (22.7)	47 (53.4)

APMO—alternating-pressure mattress overlay; *one missing data

Malnourished and end-of-life patients were excluded from the study. This requirement of the French authorities for this type of study limits the generalisation of the results, malnourished and end-of-life patients being particularly exposed to the risk of PU. This requirement was made to avoid patients leaving studies prematurely.

However, the study has strengths. All of the patients were taken into account in the analysis and there was no attrition bias. The patients studied are well described and appear to be appropriate for the type of APMO used. STROBE recommendations were followed to optimise the quality of data presentation.[29]

These clinical data, which complement technical specifications about the support surface, provide some evidence of the performance of the APMO studied in prevention of PU.

Patients were satisfied or very satisfied with the comfort and stability of the APMO in the majority of cases. The care teams assessed as very easy or easy in the majority of cases the implementation and maintenance of the APMO, and its use in terms of turning over and moving to a sitting position. The patients rated the sound level of the APMO as 'satisfactory' or 'very satisfactory' in the majority of cases. For 17 patients, the patient experiences were recorded by the staff and the family of the patient by subjective assessment, and so these criteria should be analysed with caution. No APMO-related AE was reported. Only one technical incident occurred (difficulty sliding the patient onto the shower stretcher, the mattress cover often hanging on the mattress). All of these data attest to the performance of the APMO studied.

Conclusion

In conclusion, in combination with the standard PU prevention measures, the study data indicated a low incidence of PU in the medium to high risk patients in this study, who were lying for between 15 and 20 hours a day on an APMO. JWC

Reflective questions

- On what criteria do you currently use an alternating pressure mattress overlay (APMO) for patients at risk of ressure ulcer (PU)?
- How might the results of this study change your opinion on the use of an APMO in patients at risk for PU?
- How might the results of this study change your practice on the use of an APMO in patients at risk for PU?

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