Conservative management of Anderson Type II odontoid fractures in octogenarians: is radiological union what we are searching for?

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Abstract. – OBJECTIVE: The C2 odontoid fractures represent one of the most common cervical spine injuries. Stabilization and immobility are required for a correct treatment. However, in some cases surgical treatment is recommended. There are still no guidelines for Type II odontoid fractures management. The present study aims at determining how non-union could impact on mortality, functional and clinical outcomes in octogenarian patients conservatively treated.

PATIENTS AND METHODS: The present investigation is a retrospective case series. All patients with diagnosis of Type II odontoid fractures, over 80 years and conservatively treated in our institution between January 2016 to April 2020 were potentially eligible for the study. The primary outcome was the bony fusion of the fracture after 3 months of conservative treatment. The secondary outcomes were clinical, functional outcomes and mortality.

RESULTS: Sixty-four patients were eligible for the study according to inclusion and exclusion criteria. Computer Tomography (CT) evaluation performed 3 months after trauma showed complete fracture healing in 31 patients (48.4%, Fused), while 33 patients (51.6%) were evaluated as non-fused. Among these, 6 months after the CT evaluation, 14 patients were classified as stable, while 19 were classified as unstable. There were no statistically significant changes in clinical and functional outcomes reported in our patient series between patients with complete radiological healing and patients who reported stable fibrous non-union.

CONCLUSIONS: In a selected group of elderly patients with a high risk for surgery, the conservative treatment of odontoid Type II fractures can be considered a viable management strategy. The achievement of a stable non-union allows for clinical and functional results comparable to complete fracture healing.

Key Words:
Elderly, Odontoid fracture, Conservative management, Anderson Type II, Octogenarians.

Introduction

Population aging is the most representative demographic and social phenomenon of the 21st century. Due to the decline in fertility associated with the increase in longevity, a gradual increase of elderly people (over 65 years) around the world is taking place[1].

The C2 odontoid fractures represent nowadays one of the most common cervical spine injuries (accounts for 15% of total)[2]. Population aging led to progressive incidence increase for upper cervical spine lesions in the elderly patients[3]. Stabilization and immobility are required for a correct treatment of cervical fractures. A hard cervical collar, a halo-vest immobilization, or open surgical fixation represent valid methods to achieve mechanical stability and consequently fracture healing[2]. However, mortality rates seem to be related with the fracture management, in fact the use of halo vest immobilization in the elderly patients lead to a greater risk of pneumonia, cardiac arrest and death compared to surgical treatment or immobilization with hard cervical collar[4]. Surgical treatment is recommended especially in Type II and Type III C2 odontoid fractures according Anderson Alonzo classification[5]. However, most of geriatric patients present many comorbidities and often surgery could be contraindicated. The presence of osteoporosis, an alteration of cervical spine biomechanics and a reduced blood supply to the odontoid process could result in a high rate of non-fusion in elderly patients conservatively treated[5]. While obtaining a fracture fusion represents the standard for defining fracture healing, on the other hand some authors[6,7] have argued that a stable non-union could represent an acceptable result in the elderly patients.

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Therefore, the aim of the present investigation is to evaluate the bony healing rate of Type II odontoid fractures and determine how non-union could impact on mortality, functional and clinical outcomes in a series of elderly patients conservatively treated with a rigid cervical collar.

Patients and Methods

Study Setting and Design

The present study is a retrospective analysis on consecutive patients with Type II odontoid fractures treated at our Emergency Department and consequently at our Vertebral Surgery Unit, from January 2014 to April 2020. All patients signed a written consent concerning demographic and clinical data collection for scientific purposes according to institutional protocol. The study respects national ethical standards and the Helsinki Convention. Considering that nothing different with respect to the institutional clinical and radiographic follow-up protocols was done, a formal ethical approval was not requested for this retrospective study. Patients were clinically and radiographically evaluated 1 month, 6 months, 1 year, after trauma. The present study was conducted according to CAse REports (CARE) guidelines[8].

Institutional Database and Data Collection

The data of patients affected by Type II odontoid fractures referred to our unit was collected using a standardized data collection system. From these patients, we collect demographic data (age; sex; Body Mass Index: BMI), medical history, chronic therapies, smoke addiction, American Society of Anesthesiologists (ASA) score and Charlson Comorbidity Index (CCI) and the mechanism of injury distinguished as low-energy trauma or high-energy trauma.

Inclusion and Exclusion Criteria

All patients with diagnosis of Type II odontoid fractures and over 80 years treated at our institution between January 2016 to April 2020 were potentially eligible for the study.

Inclusion criteria were: (I) Type II odontoid fracture according Anderson Alonzo classification[5]; (II) age > 80 years; (III) complete radiological and clinical data set.

Exclusion criteria were: (I) surgical treatment or Halo Vest immobilization; (II) previous axial or sub axial cervical surgery; (III) serous cognitive impairment; (IV) Parkinson or Alzheimer disease; (V) Other limb fractures during the same trauma; (VI) Metastatic spinal lesion. A protocol of study enrolment and evaluation is provided in Figure 1.

Conservative Treatment Protocol

As standard of care in our institution, all included patients were treated according to the following protocol. After diagnosis of Type II odontoid fractures, a cervical rigid collar with thoracic immobilization (Aspen Cervical-thoracic-orthosis CTO, Aspen Medical Products, Irvine, CA, USA) was placed continuously, 24 hours a day, for 8 weeks, and only rigid cervical collar for another 4 weeks. Indications for surgery were: radiological signs of high instability (fracture gap bigger than 2 mm, antero-posterior displacement of more than 5 mm or an odontoid angulation more than 10°) or neurological deficit at admission[9,10].

Radiological Evaluation

All included patients performed a cervical Computer Tomography (CT) scan with multiplanar reconstruction at Emergency Department admission. Cervical spine plain radiograph in lateral and trans-oral Antero-Posterior views were performed after 1 and 2 months. A cervical spine CT scan with multiplanar reconstruction was performed after 3 months from the trauma to evaluate the bony union of the fracture. The bony union was defined as the bone trabeculae crossing the fracture associated with continuity of the cortical line, an absence of sclerotic borders and residual gap[11]. In cases of doubtful fracture healing another cervical spine CT scans and flexion-extension radiographs in lateral view were obtained after 6 months from the trauma. On reviewed images, the following parameters were measured: (I) Fracture gap; (II) Odontoid displacement; (III) odontoid angulation; (IV) odontoid instability. All images were stored on Picture archiving and communication system (PACS) powered by Carestream Clinic Imaging Solutions. All retrieved images were reviewed, using a dedicated workstation (Advantage Windows Workstation; GE Medical Systems, Milwaukee USA), by 2 senior spinal surgeons (L.P and F.C.T.). To validate the measured parameters the inter-rater reliability (IRR) between the two observer was calculated.

Clinical Evaluation

Pain intensity evaluated using a ten itemized point visual analogue scale (VAS) was registered

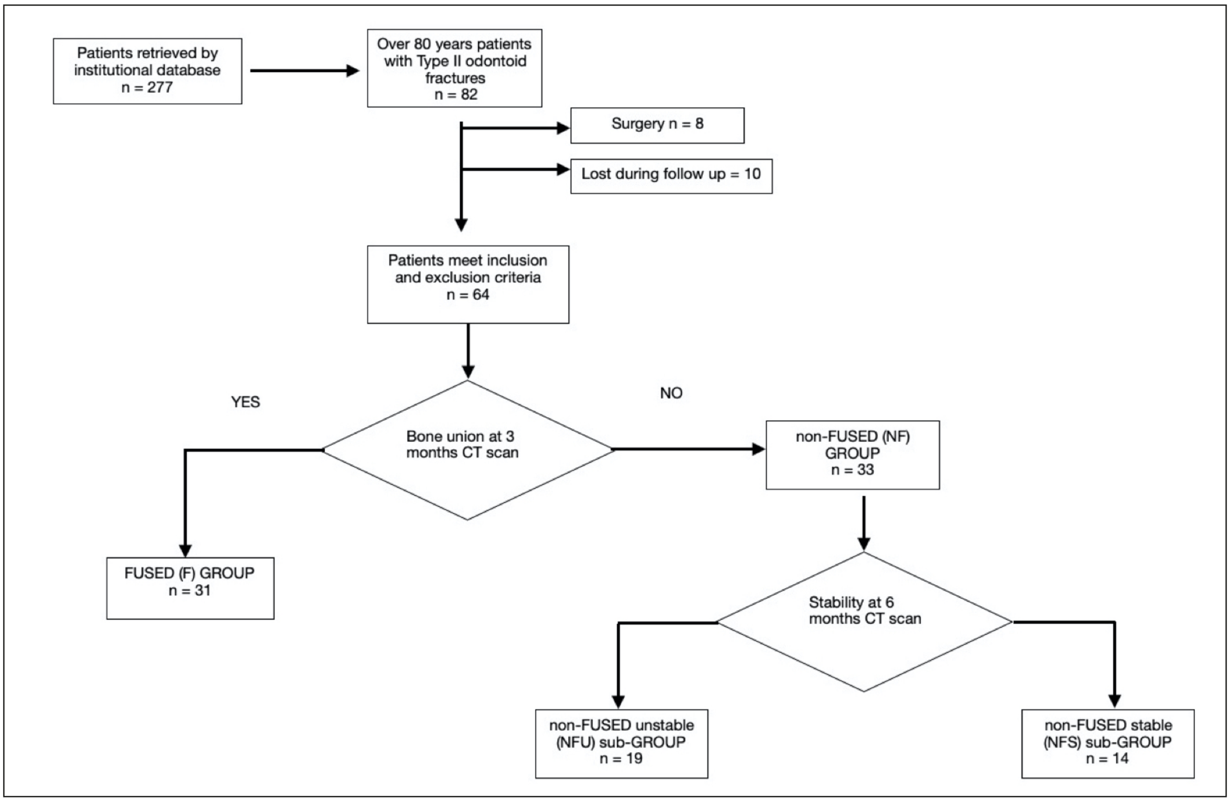

Figure 1. Flow chart of the study protocol.

at first evaluation and during all follow-up visits. Short Form 36 questionnaire (SF36), Physical component score (PCS), Neck Disability Index (NDI) was registered at first evaluation, during the 6- and 12-months follow-up visit.

Patients Assignment and Groups Setting

We defined fused (F) all patients reaching bone healing at cervical spine CT scan performed 3 months after trauma (Figure 2). All the other patients were assigned to non-fused (NF) group (Figure 3).

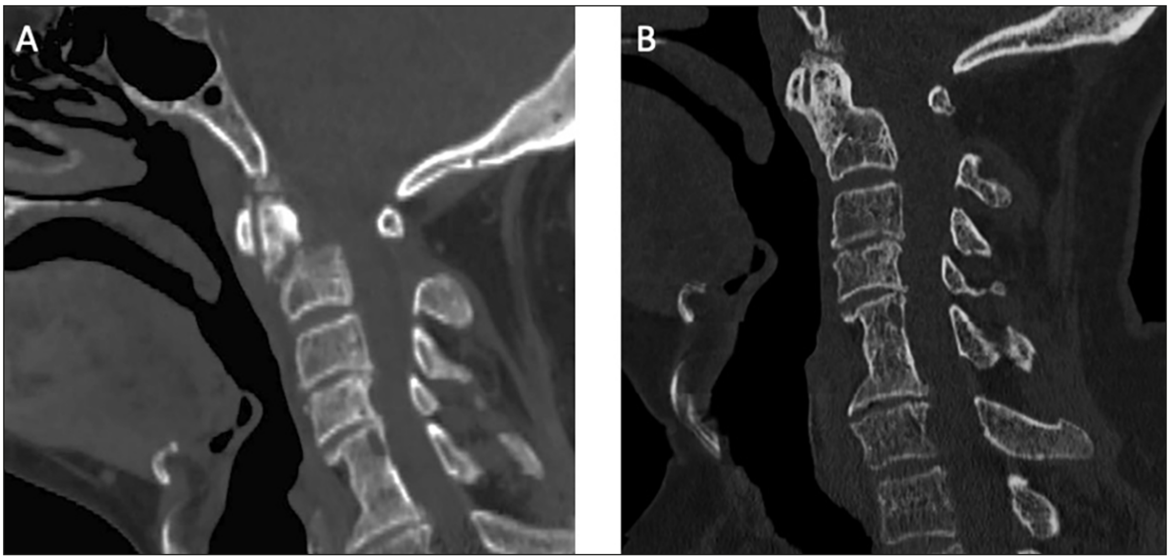

Figure 2. Case of 87 years patients belonging to F group. **A**, Bony window sagittal CT scan showing a type 2 odontoid fracture anteriorly displacement. **B**, obtaining a stable osseous callus at 3 months of follow-up.

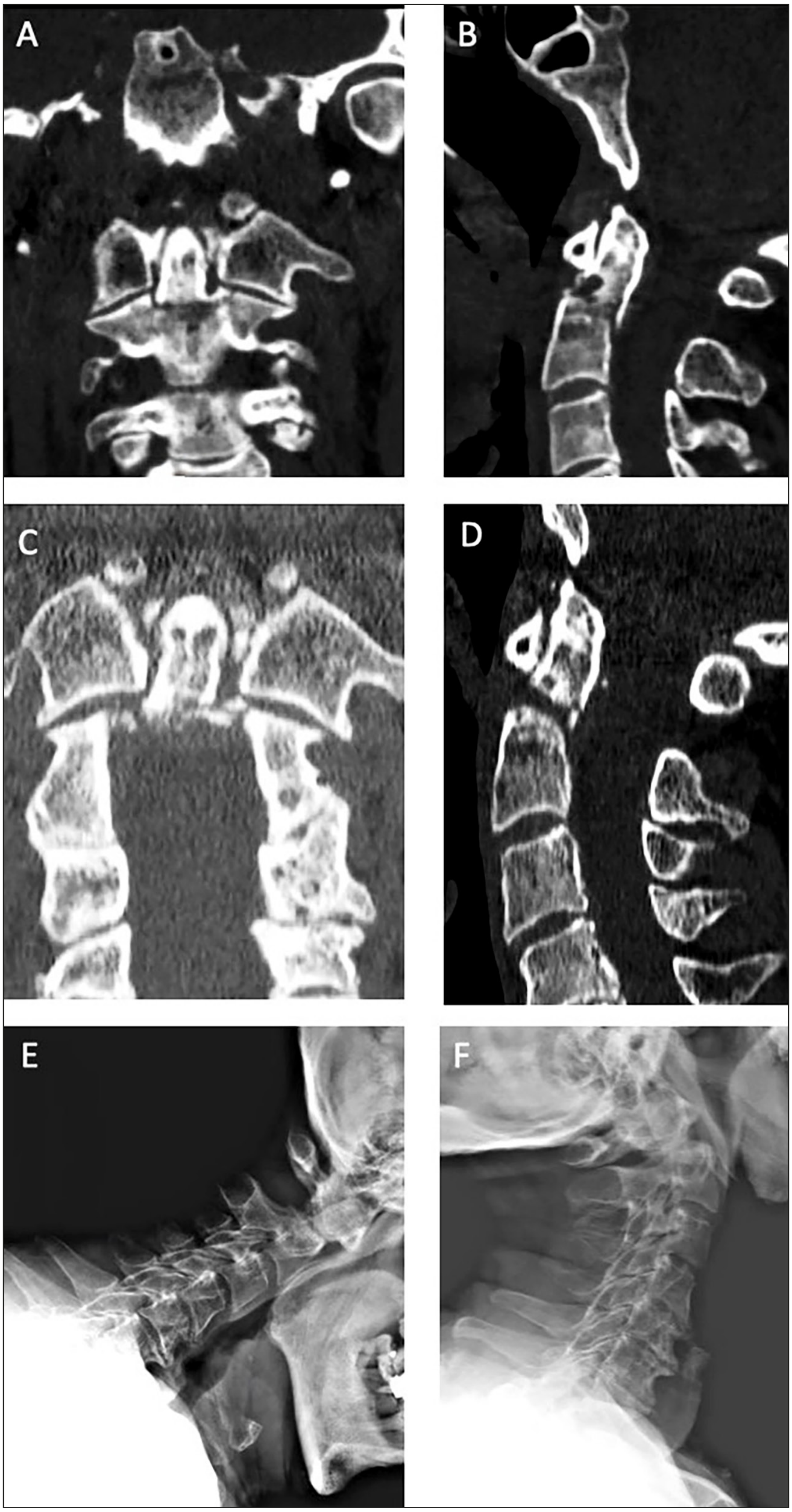

Figure 3. Case of an 84-years-old patient belonging to group NF. **A-B**, Coronal and sagittal computed tomography scans demonstrating type II odontoid fracture. **C-D**, Coronal and sagittal computed tomography scans at 6 months of follow-up shows the unfused fracture. **E-F**, Lateral cervical spine radiographs in flexion (**E**) and extension (**F**) views at 6 months of follow-up with no signs of instability.

Patients belonging to the NF group were divided in 2 subgroups, according to the stability of the fracture. We considered a Type II odontoid fracture as unstable when one or a combination of following criteria was present: (I) a posterior odontoid displacement > 2 mm between CT scan at admission and CT scan at 6 months follow-up occurred; (II) odontoid instability defined as the presence of an odontoid movement > or = 5 mm at 6 months follow-up flexion-extension radiographs. These patients were assigned to a non-fused unstable group (NFU).

The other patients belonging to NF group were subgrouped in non-fused stable group (NFS).

Outcomes

The primary outcome was the evaluation of radiological bony healing rate after 3 months of conservative treatment. The secondary outcomes were: the correlation between non fusion and clinical and functional outcomes, related event mortality and treatment related complications.

Statistical Analysis

The Student's *t*-test for continuous variables and a Chi-squared test for categorical variables were used. The Mann-Whitney test was used to compare functional outcomes. The data were checked for normality using the Kolmogorov-Smirnov test for continuous variables. A non-normal distribution was found hence it was not indicated to perform the analysis of variances with the ANOVA test. The IRR between the two evaluators was calculated using a Fleiss' kappa statistic. Reliability was considered as "moderate" for values between 0.41 and 0.60, "substantial" for values between 0.61 and 0.80, and "excellent" for values > 0.80.

The significance was established for a value of $p < 0.05$. Dedicated SPPS statistical calculation software (IBM Corp., Armonk, NY, USA) was employed. Data are presented as mean and standard deviation. Only one decimal place has been reported, rounded up.

Results

Study Population

Only 64 among the 277 patients with diagnosis of C2 odontoid fracture were eligible for the study, according to inclusion and exclusion criteria. Study protocol is provided in Figure 1. Mean age was 83.8 (+/-4.1) years. The male/female ratio was 1.46 (M: 38; F:26) and the average BMI was 27.1 (+/-6.9) kg/m^2. All fractures were classified as Type II odontoid fractures, according to Anderson-Alonzo classification[5]. In 3 cases, an associated fracture of the posterior arch of the atlas was observed. In 2 cases, a mandibular fracture was recorded.

In 53 patients (82.8%), the cause of fracture was a domestic minor fall, while in 11 patients (17.2%), a high energy trauma, such as traffic accident, was reported. Patients' features are reported in Table I.

Radiological Findings

The IRR was calculated using the Fleiss' kappa (0.732, 95% CI: 0.597-0.894). CT evaluation performed 3 months after trauma showed complete fracture healing in 31 patients (48.4%, F), while 33 patients (51.6%, NF) were evaluated as non-fused. Among these, after 6 months CT evaluation 14 patients were classified as stable (NFS), while 19 were classified as unstable (NFU). No statistically significant variation was detected on examined radiological parameters (fracture gap, posterior displacement, and odontoid obliquity) at 0, 3, 6 months CT examination. The complete measured outcomes are reported in Table II.

Clinical and Functional Outcomes

The difference of NDI score at 6 months between the two groups was statistically significant (32.6 +/- 6 *vs.* 39.3 +/- 5.3, $p = 0.0015$) and even at 12 months: 23.5 (+/- 5.6) in the F group, while 30.7 (+/- 4.1) in the NF group ($p = 0.001$). No statistically significant variation was observed in the SF36 at 12 months and VAS at 6 months between the two groups [SF 36: 49.8 (+/-6.4) *vs.* 50.2 (+/-6.1), VAS: 1.2 (+/-0.9) *vs.* 2.9 (+/-1.2)]. The complete outcomes are reported in Table III.

Complications and Mortality

The complication rate appears similar among the two groups (6.5% for F group *vs.* 12.1% for NF group), with non-statistical significance. However, in the NF group, and specifically in NFU, 2 patients developed C1-C2 myelopathy requiring surgical decompression performed respectively 13 and 14 months after the trauma.

In the F group, only one patient died 11 months after the trauma (3.2%), while in the NF group 7 patients died; among these, 5 died before completing 12 months follow-up and 2 patients died 14

Table I. Patients' demographics and features of trauma (expressed in mean and standard deviation and percentages).

	Fused group (F)	Non-fused group (NF)	Subgroup non-fused Stable (NFS)	Subgroup non-fused Unstable (NFU)
No. of patients	31 (48.4%)	33 (51.6%)	14 (42.4%)	19 (57.6%)
Age	84.2 (+/-3.8)	83.4 (+/3.5)	83.3 (+/-6.3)	83.5 (+/-3.9)
Sex	11 F; 20 M	15 F; 18 M	5 F; 9 M	10 F; 9 M
BMI	27.4 (+/-8.2)	26.9 (+/-6.8)	26.3 (+/-5.3)	27.1 (+/-4.9)
ASA				
1	0	0	0	0
2	13 (41.9%)	6 (18.2%)	6 (42.8%)	0
3	18 (48.1%)	27 (81.8%)	8 (57.2%)	19 (100%)
CCI				
1	4 (12.9%)	0	0	0
2	7 (22.5%)	4 (12.1%)	4 (28.6%)	0
3	10 (32.2%)	7 (21.2%)	4 (28.6%)	3 (15.8%)
4	8 (25.8%)	5 (15.1%)	3 (21.4%)	2 (10.5%)
5	0	5 (15.1%)	3 (21.4%)	2 (10.5%)
> = 6	2 (6.5%)	12 (36.4%)	0	12 (63.2%)
Mortality	1 (3.2%)	7 (21.2%)	0	7 (36.8%)
Complication	2 (6.5%)	4 (12.1%)	0	4 (21%)
Collar decubitus lesion	2 (6.5%)	1 (3%)	/	1 (5.2%)
Myelopathy	0	2 (6.1%)	/	2 (10.5%)
Bed rest syndrome	0	1 (3%)	/	1 (5.2%)
Trauma				
High energy	4 (12.9%)	7 (21.2%)	3 (21.4%)	4 (21%)
Low energy	27 (87.1%)	26 (78.8%)	11 (78.6%)	15 (79%)
Associated lesion	7 (22.5%)	6 (18.2%)	2 (14.2%)	4 (21%)
Head trauma	4 (12.9%)	4 (12.1%)	1 (7.1%)	3 (15.8%)
Mandibular fracture	1 (3.2%)	1 (3%)	0	1 (5.2%)
C1 fracture	2 (6.5%)	1 (3%)	1 (7.1%)	0
Follow up (months)	13.8 (+/-3.7)	13 (+/-2.6)	13.7 (+/-1.7)	12.6 (+/-1.3)

months after the trauma. However, Kaplan-Mayer curves performed on mortality showed non statistical significance among the two groups (Figure 4).

Subgroup Analysis

Patients of NF group were stratified according to the stability of fracture at cervical spine CT scan performed 6 months after the trauma. In the NFS group there were 5 female patients (35.71%) while in the NFU group 10 patients (52.63%). The mortality rate was 36.8% (7 patients) in the NFU group. Moreover, in this group, 4 patient (21%) reported complications: 1 collar decubitus lesion (5.2%), 2 myelopathy (10.5%), 1 bed rest syndrome (5.2%).

No significant statistical difference was reported in the fracture gap between the two groups. However, the difference of posterior displacement at 6 months between NFS and NFU was statistically significant [NFS posterior displacement: 1.9 (+/-0.6) *vs.* NFU 4.2 (+/-0.7) $p = 0.0026$] and also odontoid obliquity at 3 and 6 months [NFS odontoid obliquity at 3 months: 5.5 (+/-1.4) *vs.* NFU odontoid obliquity 9.3 (+/-1.2); $p = 0.0035$. NFS odontoid obliquity at 6 months 5.8 (+/-1.7) *vs.* NFU odontoid obliquity 9.8 (+/-1.5); $p = 0.0028$].

Furthermore, there was a statistically significant variation between the two groups in VAS, NDI score and SF36. In fact, VAS at 3 months in the NFS group was 2.4 (+/-1.8), while in the NFU group was 3.7 (+/-1.2), $p = 0.037$. At 6 months, VAS was 1.7 (+/-1.1) in the first group, while 3.5 (+/-1.3) in the second one ($p = 0.023$). As regards to NDI score, at 6 months it was 34.6 (+/-6.7) in the NFS group, while 41.3 (+/-4.9) in the NFU group ($p = 0.002$). At 12 months, it was 27.8 (+/-4.5) in the first group, while 33.4 (+/-5.7) in the second one ($p = 0.0012$). Finally, concerning the SF36, at 6 months it was 38.5 (+/-5.4) in the NFS group while 42.4 (+/-6.4) in the NFU group ($p = 0.026$). At 12 months, SF36 was 47.8 (+/-5.8) in the stable group, while 52.5 (+/- 5.4) in the unstable group ($p = 0.039$).

Table II. Main radiologic parameters.

	Fused group (F) n = 31	Non-fused group (NF) n = 33	Subgroup non-fused		*p*-value F *vs.* NF	*p*-value NSF *vs.* NFU
			Stable (NFS) n = 14	Unstable (NFU) n = 19		
Fracture gap t0 (mm)	1.4 (+/-0.3)	1.5 (+/-0.6)	1.5 (+/-0.3)	1.6 (+/-0.7)	> 0.05	> 0.05
Fracture gap 3 months (mm)	/	1.7 (+/-0.2)	1.6 (+/-0.8)	1.8 (+/-0.4)	/	0.239
Fracture gap 6 months (mm)	/	1.8 (+/-0.4)	1.5 (+/-0.7)	1.9 (+/-0.4)	/	> 0.05
Posterior displacement t0 (mm)	2 (+/- 0.8)	1.67 (+/-0.6)	1.4 (+/.0.6)	1.7 (+/-0.6)	0.17	0.127
Posterior displacement 3 months (mm)	/	2.5 (+/-0.6)	1.8 (+/-0.5)	2.8 (+/-0.7)	/	0.152
Posterior displacement 6 months (mm)	/	3.1 (+/-0.9)	1.9 (+/-0.6)	4.2 (+/-0.7)	/	0.0026
Odontoid obliquity t0 (degree)	5.3 (+/- 1.2)	5.1 (+/-2.1)	4.6 (+/-1.1)	5.3 (+/-1.7)	> 0.05	> 0.05
Odontoid obliquity 3 months (degree)	6.1 (+/-1.9)	7.3 (+/-1.7)	5.5 (+/-1.4)	9.3 (+/-1.2)	0.32	0.0035
Odontoid obliquity 6 months (degree)	/	7.9 (+/-2.1)	5.8 (+/-1.7)	9.8 (+/-1.5)	/	0.0028
Odontoid instability (mm)	/	7.7 (2.1)	1.3 (+/-0.8)	8.3 (+/-1.1)	/	0.0037

Discussion

Although Type II odontoid fractures are among the most frequent cervical injuries, there are still no guidelines on therapeutic management to be adopted in the literature[7]. The topic is even more unclear when regarding elderly patients[6,7]. In the elderly population, the 1-year mortality rate associated with C2-odontoid fractures ranges from 4% to 42%, comparable with femoral neck fractures mortality rate, indicating a potential end-of-life event for elderly patients[3,12]. Some studies highlighted the risk factors associated with mortality and treatment failure of odontoid Type II fractures in the elderly. In particular, Bajada et al[13], in a retrospective review of 83 elderly patients, demonstrated that low serum hemoglobin and the presence of a neurologic deficit at hospitalization were independent predictors of mortality at 30 days, while a low hemoglobin level, a neurological deficit and Type III fractures were independent predictors of one-year mortality[13]. It has been previously suggested[3] that mortality rates also

Table III. Principal clinical and functional outcomes.

	Fused group (F) n = 31	Non-fused group (NF) n = 33	Subgroup non-fused		*p*-value F *vs.* NF	*p*-value NSF *vs.* NFU
			Stable (NFS) n = 14	Unstable (NFU) n = 19		
VAS t0	7.9 (+/-2.1)	7.5 (+/-2.3)	7.7 (+/-2.8)	7.3 (+/1.9)	0.132	> 0.05
VAS 3 months	2.3 (+/-1.2)	3.4 (+/-1.4)	2.4 (+/-1.8)	3.7 (+/-1.2)	0.114	0.037
VAS 6 months	1.3 (+/-0.9)	2.9 (+/-1.2)	1.7 (+/-1.1)	3.5 (+/-1.3)	0.078	0.023
NDI t0	56.1 (+/-8.4)	61.2 (+/-6.5)	61.3 (+/-7.2)	60.7 (+/-5.2)	> 0.05	> 0.05
NDI 6 months	32.6 (+/-6)	39.3 (+/-5.3)	34.6 (+/-6.7)	41.3 (+/-4.9)	0.0015	0.002
NDI 12 months	23 (+/-5.6)	30.7 (+/-4.1)	27.8 (+/-4.5)	33.4 (+/-5.7)	0.001	0.0012
SF-36 t0	26.1 (+/-7.8)	26.2 (+/-2.9)	26.3 (+/-4.2)	25.4 (+/-3.6)	> 0.05	> 0.05
SF-36 6 moths	40.5 (+/-8.6)	40.8 (+/-4.9)	38.5 (+/-5.4)	42.4 (+/-6.4)	0.233	0.026
SF-36 12 months	49.8 (+/-6.4)	50.2 (+/-6.1)	47.8 (+/-5.8)	52.5 (+/-5.4)	0.118	0.039

NDI, neck disability index; SF-36, short form 36; VAS, visual analogue scale.

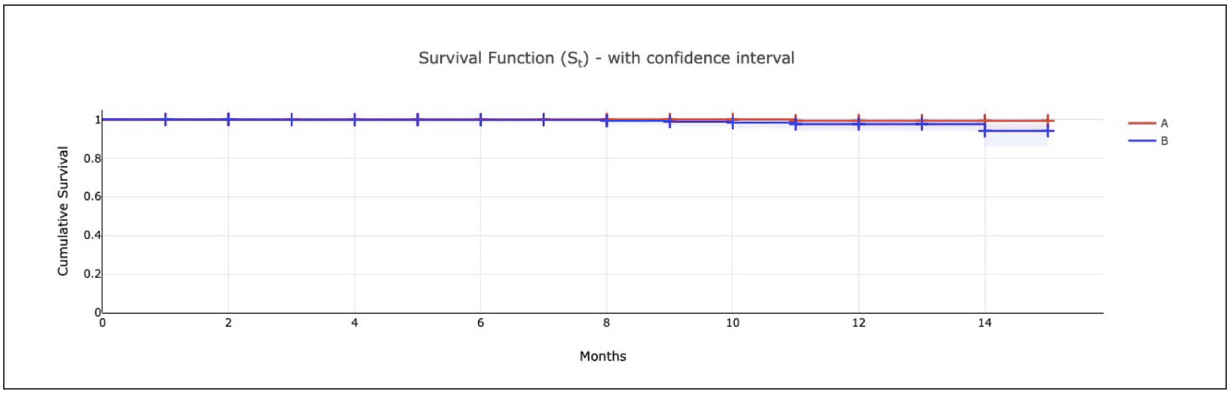

Figure 4. Kaplan-Mayer curves representing survival among the two groups: fused and not fused.

correlate with fracture management. In our cohort, the mortality rate was 12.5%, consistent with literature. However, even if the difference seems not to be statistically significant, the mortality rate was 3.5% in the F group and 21.2% in the NF group. Furthermore, if we consider only the NSU group, the mortality rate increases to 36.8%. Therefore, the presence of unstable non-union could represent a risk factor for mortality.

Considering the radiological outcomes, in all patients after CT evaluation at 6 months follow-up, the gap between fracture fragments was < 2 mm, the posterior odontoid displacement < 5 mm and odontoid obliquity < 10°. A complete fracture healing was observed in 48.4% of patients at 3 months CT evaluation, and this is in range with previous literature reports[6]. On the other hand, only 14 patients (21.9%) showed a stable fibrous non-union in disagreement with the ranges reported in the literature[6,7]. Unlike the findings of other studies[7,14-16], two patients in our series developed C1-C2 myelopathy requiring surgery after 13 and 14 months, respectively. Both patients belonged to the NFU group. Therefore, cervical spine MRI should be routinely performed in elderly patients with odontoid fractures, especially if on conservative treatment[17].

Despite some authors[5,18] in literature have shown how surgery decreases the mortality rate in the short term and long term and significantly improves functional status in the elderly population with Type II odontoid fractures, other authors[15,19] have sustained that no advantage has been observed in surgical treatment over conservative treatment in terms of functional outcome in this population, even if a complete healing of fracture has been reached only in a few patients[15-20]. This discrepancy could be explained by the formation of a fibrous callus in most patients. Patel et al[21], in fact, have shown that stable fibrous non-union ensures acceptable clinical and functional outcomes in these patients.

In our series, discrete functional outcomes have been reported in all patients. In fact, the NDI, SF36 and VAS had improved in both groups between pre-treatment values and last follow-up values and these changes have resulted to be statistically significant.

The fracture stability, defined as the absence of the odontoid process displacement on the cervical spine X-ray with dynamic projections in maximum flexion and extension performed 6 months after the trauma[7], was found to be a necessary condition in our patients to start a gradual removal of rigid cervical collar.

There were no statistically significant differences in clinical and functional outcomes reported in our patient series between patients with complete radiological recovery (group F) and patients who reported stable fibrous non-union (group NFS). Therefore, obtaining this result may be considered as a sufficient goal in patients over 80 with a Type II odontoid fracture. The use of the rigid cervical collar represents a safe and effective method to achieve this result[6,7]. Furthermore, a shorter hospitalization in patients managed conservatively could reduce the exposure to nosocomial infectious disease, especially during the present SARS-CoV-2 pandemic[22,23].

Limitations

The present investigation is not free from limitations. In fact, the retrospective design and the strictly selected patients group represent a handicap to draw generalizations; therefore, these results must be critically interpreted. Furthermore, the absence of any control group and the small patient number could negatively affect the level of evidence of this study.

Conclusions

Doubtless the optimal result to obtain remains the fracture bony union achievement. However, the presence of fracture stability, even in the absence of a bony union, may represent an acceptable result in terms of clinical and functional outcome in octogenarians with Type II odontoid fracture. Anyhow, in a selected group of elderly patients with a high risk for surgery, the conservative treatment of odontoid fractures with a hard cervical collar (during bed rest, sitting and standing position) for a period of 10-12 weeks could be considered a viable management strategy, provided that the fracture is stable and with a low risk of neurologic impairment. In these patients, however, an accurate follow-up protocol must be designed to ensure that the result is achieved. Despite the present study is a case series of patients treated conservatively in our institution, we have tried to add quality to the evidence supporting the recommendation for the use of hard cervical collars during nonoperative treatment of elderly odontoid fractures.

Conflict of Interest
The Authors declare that they have no conflict of interests.

Acknowledgements
None.

Informed Consent
All patients signed a written consent concerning demographic and clinical data collection for scientific purposes according to institutional protocol.

Ethics Approval
The study respects national ethical standards and the Helsinki Convention. Considering that nothing different with respect to the institutional clinical and radiographic follow-up protocols was done, a formal ethical approval was not requested for this retrospective study.

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Authors' Contribution
DC, AP, DAS conceived and designed the study. All authors contributed to the preparation of the materials, the conception of the database and the collection of data. AP, MIB and CV performed the data analysis. DC, AP, GGM wrote the first draft of the manuscript. FCT, LP, GZ and MG corrected and edited the first draft. All authors read and approved the final manuscript.

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Data Availability
The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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