would not be feasible to do a comparison with the standard version. Subjects with normal hearing performed slightly better on the standard MMSE. As the written version was in large font, it is unlikely that this was due to visual problems, but visual acuity was not formally tested.

A written version of the test has been previously used in Alzheimer’s dementia, having a trend to superior scores with the standard version in hearing-impaired subjects and the converse in hearing-unimpaired subjects [6]. The authors suggested that this supported a non-artefactual correlation between cognitive and hearing impairment. Our results suggest that the written MMSE is comparable but not superior to the standard MMSE in a population with normal or mildly impaired cognitive function. However, the written MMSE was preferred to the standard version in the hearing-impaired group, presumably because it required less effort, with no significant preference in the normal hearing group.

Audiometry was not used to stratify subjects. As we were evaluating a test for clinical practice, the use of the (bedside) whisper test had some advantages. A possible source of bias was the variation in the baseline characteristics of the target population. However, the analysis was adjusted for gender and age as much as possible.

The written MMSE was thus comparable to the standard MMSE in a population which included subjects with normal and impaired hearing and cognition. Hearing-impaired subjects performed no better with the written version but preferred it, suggesting that the written MMSE may be a more acceptable version of this test in the hearing impaired. In subjects with profound hearing Impairment, the standard version of the MMSE is clearly impractical and in this group, the written version is indispensable.

Key points
- The written MMSE produced similar scores to the standard version in normal and hearing-impaired patients.
- Most hearing-impaired patients preferred the written version.
- The written MMSE or an equivalent is essential in patients with profound deafness.

Acknowledgements
Maneesha De Silva was supported by a Otago Postgraduate Medical Society Summer Studentship.

Table 2. Comparison of the standard and written Mini-Mental Examination scores

<table>
<thead>
<tr>
<th></th>
<th>Normal hearing (n = 55)</th>
<th>Hearing impaired (n = 27)</th>
<th>All subjects (n = 82)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard test</td>
<td>25.8 ± 3.6</td>
<td>25.4 ± 4.0</td>
<td>23.9 ± 0.4</td>
</tr>
<tr>
<td>Written test</td>
<td>24.9 ± 4.2</td>
<td>25.4 ± 3.3</td>
<td>23.5 ± 0.4</td>
</tr>
<tr>
<td>Difference</td>
<td>0.84 ± 0.3</td>
<td>0.02 ± 0.4</td>
<td>0.41 ± 0.3</td>
</tr>
</tbody>
</table>

Conflicts of interest
We do not have any commercial interest in this research and any other conflicts of interest with respect to this paper.

References

ERCP in octogenarians: a safe and efficient investigation
SIR—The demographic development in the Western world and in some developing countries over the coming decades will lead to higher incidence of aged population [1].

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Factors contributing to these demographic changes include improvements in primary prevention, advances in acute medical care, and progress in pharmaceutical and biomedical technology. Simultaneously, patients and their relatives have greater expectations from health care than previously. As the ability to treat illness increases, the potential for iatrogenic disease may grow proportionately. In this dynamic situation, physicians must continuously evaluate the manner in which they address the health care requirements of older patients. In this context, not only the increasing longevity but also the improvement in performance status must be considered. In the past, there has been a reluctance to consider older patients for non-critical endoscopic interventions, because of the perceived drop in safety and tolerance as well as lack of substantive benefits [2–5].

While some trials had already addressed the safety of performing endoscopic retrograde cholangio-pancreatography (ERCP) in elderly patients [6, 7] in a retrospective study design, in our trial we included the largest number of patients over 80 years published so far in a prospective study design.

Methods

During a 3-year period a total of 1,960 ERCP procedures were performed at our department. The study population comprised of 118 consecutive patients of age ≥80 years (mean age 84.5 ± 4.3 years, range 81–95 years; 77 male; American Society of Anaesthesiology (ASA) class III: 47 patients and ASA class IV: 36 patients) who underwent 195 procedures. The indication was proposed strictly; in most cases MRCP or EUS were performed before ERCP, whenever possible. The remaining 1,195 patients of age ≤80 years (mean age 61.5 ± 21.2 years, range 17–80 years, 478 male; ASA class III: 282 patients, ASA class IV: 101 patients) who underwent an ERCP during the same time period served as a control group, and procedural and sedation-related complications, which were retrospectively derived from an endoscopic complication database of our institution, were compared with those of the patients aged ≥80 years.

According to the ASA physical status classification [8], the majority of the patients of age ≥80 years were in ASA class III and IV.

Post-procedural pancreatitis was defined according to the 1991 consensus guidelines [9]. Immediate post-sphincterotomy bleeding consisted of endoscopic evidence of venous oozing that required local injection of 1:10,000 solution of epinephrine for control of haemorrhage.

Sedation-related complications were defined as hypoxaemia (oxygen desaturation <90%), hypotension (systolic blood pressure <90 mmHg) and bradycardia (heart rate <50 bpm).

All examinations in octogenarians were performed by experienced investigators who had performed more than 1,000 ERCP examinations each. The patients were positioned on the left side, and only therapeutic duodenoscopes were used (TJF 140 R, Olympus Optical, Hamburg, Germany).

The investigations were performed under sedation with midazolam (Dormicum, Hoffmann-LaRoche, Grenzach/Whylen, Germany) if necessary in combination with meperidine (Dolantin, Aventis, Frankfurt, Germany) or propofol (Propofol 1% Fresenius-Kabi, Fresenius-Kabi, Bad Homburg, Germany) alone. Choice of type of sedation was left to the endoscopists. According to the current German guidelines on the use of propofol as a sedative, an assisting physician with intensive care training performed the propofol sedation. The assisting physician was not involved in the endoscopic procedure but was solely responsible for sedation and observation/documentation of the vital signs.

Heart rate, oxygen saturation (under continuous oxygen supplementation with 2 l/min via nasal cannula) and blood pressure (every 5 min) were continuously monitored. All patients received an intravenous infusion of normal saline via peripheral venous access at a rate of 500 ml/h.

All sedation-related complications were documented. None of our procedures were undertaken as day case procedures and all patients were observed as inpatients for at least 72 h to evaluate their clinical outcome.

Results

In the group of 118 patients, a mean number of 1.65 ± 0.3 ERCPs were performed. The leading indication for ERCP was biliary obstruction in 87 cases (73.7%), and 23 patients (16.8%) underwent the procedure due to emergency indications (biliary pancreatitis, n = 10; acute cholangitis, n = 7; biliary leakage after cholecystectomy, n = 4; haemobilia, n = 2). Only eight patients (6.8%) underwent a diagnostic procedure.

The most common endoscopic findings at initial ERCP were bile duct stones followed by malignant biliary stenosis caused by pancreatic or bile duct carcinoma (Table 1).

The most frequently performed procedures were biliary (n = 69) and pancreatic (n = 4) sphincterotomy, common bile duct (n = 57) and pancreas duct (n = 3) stenting and endoscopic papillectomy (n = 3).

Reversal of jaundice was possible in 81 of 87 cases (93%) at the first attempt and in 6 patients at the second ERCP. A successful stone extraction was only possible in 36 of 49 cases (73%) in the first setting, and in 5 cases three interventions were needed. There were mostly multiple (n = 21), big (>2 cm, n = 19) or complicated stones (Mirizzi’s syndrome, n = 5, simultaneous stenosis of the bile duct n = 7) rendering stone extraction difficult.

Post-ERCP pancreatitis was the most common complication and occurred in 8 of 195 procedures (4.2%). Furthermore, post-sphincterotomy bleeding was seen in 3 of 73 cases (4.1%) but could be managed endoscopically by injection therapy in all cases. In patients aged under 80 years post-ERCP pancreatitis occurred in 72 of 1,765 ERCP procedures (4.1%); post-sphincterotomy bleedings
were seen in 27,623 cases (4.3%) but could also be managed endoscopically by injection therapy in all cases.

Sedation was performed with midazolam alone or in combination with either meperidine or propofol. The mean dose of midazolam was 6.2 ± 2.7 mg (range, 2.5–20 mg), that of meperidine 50 ± 25 mg (range, 25–200 mg) and the mean propofol dose was 318 ± 205 mg (range, 40–900 mg), respectively.

A fall of the oxygen saturation below 90% was seen in two patients, one in each sedation regimen. The patient in the midazolam/meperidine group was managed with additional oxygen administration and gentle taps on his back, the other patient who was under propofol sedation required short mask ventilation (< 5 min) due to an oxygen saturation below 85%. A drop of the systolic blood pressure below 90 mmHg was documented in five patients, all without severe consequences. One patient who developed atrial fibrillation during ERCP under sedation with propofol underwent successful electrical cardioversion within 2 h of the (completed) endoscopic intervention.

Sedation-associated complications were comparable with the retrospectively acquired data of the control group, which are shown in Table 2. In the control group there was no need for mask ventilation and no clinically relevant hypotension occurred.

**Discussion**

A number of studies have demonstrated the feasibility and safety of diagnostic endoscopic procedures in geriatric patients [10]. More recent data also report on the safety and efficacy of interventional endoscopy in patients with advanced age [3, 6, 7, 11–19]. The present prospective study focussed on patients aged 80 years or more, incorporating their ASA physical status and sedation-related complications under different sedation regimens compared to younger patients investigated during the same period.

The observed overall morbidity of 9.3% in our group of 118 octogenarians was low and comparable with literature data from younger cohorts of patients [6, 20, 21]. One of the reasons for this finding might be the operator experience, which has been shown to be an important factor for low complication rates in endoscopy [21].

The complication rates observed in our study are otherwise comparable to those reported in the literature and compare favourably with those reported in other high-risk groups [6, 16, 17]. In a retrospective study by Sugiyama et al. [13] the early complication rate for endoscopic sphincterotomy for bile duct stones in patients aged ≥90 years was comparable to younger patients in the control group (aged 70–89 years). In a recent retrospective study by Katsinelos et al. [15] evaluating the efficacy and safety of therapeutic ERCP in patients aged ≥90 years with a younger control group, the rate of post-ERCP complications

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**Table 1.** Final diagnoses in 118 patients 80 years of age or older undergoing ERCP

<table>
<thead>
<tr>
<th>Diagnoses</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bile duct stones</td>
<td>49</td>
</tr>
<tr>
<td>Extraction 1. Setting</td>
<td>36</td>
</tr>
<tr>
<td>Extraction 3. Setting</td>
<td>5</td>
</tr>
<tr>
<td>Bile duct stenting</td>
<td>2</td>
</tr>
<tr>
<td>Minimal-invasive surgery for Mirizzi’s syndrome</td>
<td>4</td>
</tr>
<tr>
<td>Stone left in the bile duct</td>
<td>2</td>
</tr>
<tr>
<td>Malignant bile duct stenosis</td>
<td>26</td>
</tr>
<tr>
<td>Pancreatic carcinoma</td>
<td>17</td>
</tr>
<tr>
<td>Bile duct carcinoma</td>
<td>6</td>
</tr>
<tr>
<td>Gallbladder carcinoma</td>
<td>2</td>
</tr>
<tr>
<td>Liver metastasis</td>
<td>1</td>
</tr>
<tr>
<td>Benign bile duct stenosis</td>
<td>9</td>
</tr>
<tr>
<td>Papillary adenoma</td>
<td>3</td>
</tr>
<tr>
<td>No pathology</td>
<td>21</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>13</td>
</tr>
</tbody>
</table>

Please note that multiple diagnoses may be present in a single patient.

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**Table 2.** Sedation and associated complications in patients aged >80 years and patients ≤80 years

<table>
<thead>
<tr>
<th>Patients</th>
<th>&gt;80 years</th>
<th>≤80 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation regime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Investigations</td>
<td>90</td>
<td>353</td>
</tr>
<tr>
<td>Mean drug dosage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midazolam plus meperidine</td>
<td>6.2 ± 2.7 mg (range, 2.5–20 mg)</td>
<td>6.0 ± 2.9 mg (range, 3.0–20 mg)</td>
</tr>
<tr>
<td>Propofol</td>
<td>105</td>
<td>1,412</td>
</tr>
<tr>
<td>Oxygen saturation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50%</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&lt;85%</td>
<td>—</td>
<td>3</td>
</tr>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;90 mmHg</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Heart rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;100 bpm.</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>&lt;50 bpm.</td>
<td>—</td>
<td>2</td>
</tr>
</tbody>
</table>

All differences of complications between both groups were statistically not significant (by Fisher exact test).
was low in both groups (6.3% versus 8.4%). Similar results were seen by Fritz et al. [7] with a complication rate of 6.8% in patients 80 years of age compared to 5.1% in the younger control group. The well reported drop in pancreatic exocrine secretion in the elderly might be one of the reasons for protecting these patients against severe pancreatitis [6, 21, 22]. In addition to the low morbidity in our patient group we did not find any mortality in our patients observed for at least 72 h.

With respect to sedation-associated complications, no adverse outcomes related to oxygen de-saturation or hypotension occurred [6, 18]. There have been only a small number of prospective studies specifically evaluating the incidence of oxygen de-saturation and hypotensive episodes in octogenerians during ERCP. Morbidity and mortality due to sedation are mostly related to hypoxaemia [23].

We found no significant difference regarding the occurrence of oxygen de-saturation or of hypotensive episodes compared to the control group despite the administration of nearly equivalent mean drug doses in both groups. This might be explained by the fact that all our patients received either supplemental nasal oxygen as well as an intravenous infusion of saline throughout the procedure.

Under this aspect, one might argue that the high midazolam dosage used in our study of older patients could represent a potential risk factor of procedural hypoxaemia. The high-mean dose of midazolam can be explained by the fact that most of our procedures were prolonged interventional endoscopies.

Overall, the administration of propofol even in our high-risk patients did not lead to a higher prevalence of sedation-associated complications. This confirms the results of our own randomised controlled trial based on the sedation for routine ERCP in high-risk octogenerians [18]. Similar results were also reported by Heuss et al. [19] in a recent prospective controlled study evaluating propofol sedation for endoscopy (gastroscopy, colonoscopy) in 642 high-risk patients classified as ASA III and IV compared to 642 patients at ASA class I and II. There was a slight decrease in oxygen de-saturation under propofol in patients at ASA class III and IV, all without severe consequences, while the mean decrease in arterial blood pressure and heart rate was greater in patients at ASA class I and II.

Regarding the clinical impact of ERCP in elderly patients, biliary obstruction was the most common clinical presentation and it was mainly caused by choledocholithiasis followed by malignant stenosis due to pancreatic or bile duct carcinoma.

According to our success rate of 93% for the reversal of obstructive jaundice, endoscopic interventions should be the procedure of first choice even if repeated sessions are needed in complicated situations, e.g. due to multiple and large stones. This explains our relatively high-mean number of 1.7 ± 0.3 ERCPs performed per patient.

Furthermore, post-ERCP pancreatitis as well as post-interventional bleeding occurred in a comparable frequency in octogenerians and younger patients. However, this comparison must be interpreted with caution as our control group was analysed retrospectively.

Summarising our prospective trial in octogenerians, ERCP was performed almost exclusively with a therapeutic intention and was carried out with a high technical success rate. We found both a low procedural as well as a low sedation-associated complication rate when compared with data from a control group of younger patients. Advanced age should therefore no longer be regarded as a relative contraindication to ERCP, if indicated.

### Key points

- The demographic development will lead to a rise in endoscopic examinations in older patients. Especially in long-lasting interventional procedures like ERCP, the clinical value in geriatric patients depends on the technical feasibility and safety of the procedure.
- Therefore, we evaluated indication, type of sedation, procedure type, endoscopic findings and complications in a prospective study of 118 consecutive patients older than 80 years who underwent an ERCP over a 3-year period. Procedural and sedation-related complications were retrospectively compared with 1,195 patients aged ≤80 years undergoing an ERCP during the same time period.
- Biliary obstruction was the most common clinical presentation and it was mainly caused by choledocholithiasis followed by malignant stenosis due to pancreatic or bile duct carcinoma, with a success rate of 93% for the reversal of obstructive jaundice. However, repeated sessions are needed in complicated situations, e.g. due to multiple and large stones.
- Procedural as well as sedation-associated complication rate was also low when compared with data from a control group of younger patients. Advanced age should therefore be of no contraindication to ERCP, if indicated.

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Till Wehrmann received financial support for research by Fresenius-Kabi, Germany and speakers fees from Altana Pharma and Flak Pharma, Germany.

### Conflict of Interest

None
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**Andrea Riphaus**, **Nikos Stergiou, Till Wehrmann**

Department of Internal Medicine (Gastroenterology and Interventional Endoscopy), Roesebeckstr. 15, 30449 Hannover
Hospital Siloah, Teaching Hospital of Hannover Medical School, Germany

Email: ariphaus@web.de

**References**