

## Oxygenating mouthguard alleviates hypoxia during gastroscopy

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**A randomized study was carried out to determine the effect of oxygen (3 liters/min) via a novel oxygenating mouthguard (Oxyguard™) on arterial oxygenation in 242 intravenously sedated patients undergoing gastroscopy. In another group of 21 patients, a randomized crossover study of arterial oxygen saturation using either the standard mouthguard or the oxygenating mouthguard (3 liters/min) was conducted. Significant O<sub>2</sub> desaturation (pulse oximeter reading <90%) occurred in 25% of patients on room air but only 3% of those on oxygen ( $p < 0.001$ ). Severe desaturation (reading <85%) occurred in 5% of patients on room air but was prevented by the oxygenating mouthguard. Minimum oxygen saturation levels were significantly higher in patients on oxygen ( $90.5 \pm 0.3\%$ ) than on air ( $86.5 \pm 0.5\%$ ;  $p < 0.001$ ). In the crossover group, O<sub>2</sub> saturation was uniformly higher in the recordings of all patients using the oxygenating mouthguard. In conclusion, administration of oxygen via the oxygenating mouthguard alleviates hypoxemia during gastroscopy and prevents severe oxygen desaturation. However, hypoxemia may occur even during use of supplemental oxygen. Hence, monitoring of arterial oxygenation is recommended. (Gastrointest Endosc 1992;38:415-417)**

With use of intravenous sedation, patients undergoing endoscopy may become hypoxic.<sup>1-4</sup> Hypoxemia can be alleviated by oxygenating the patient using nasal prongs,<sup>5,6</sup> but this is inconvenient both for the patient and the endoscopist as it requires added equipment and care. A device which combines the delivery of oxygen to the nose and mouth with a regular endoscopy mouthguard has recently become available. The purpose of our study was to examine the effectiveness of this new device in oxygenating patients who were undergoing gastroscopy.

### PATIENTS AND METHODS

Two hundred forty-two consecutive, unselected patients undergoing elective gastroscopy at the Centre for Digestive Diseases participated in this study. The indications for the endoscopic procedure included abdominal pain, heartburn, anemia, weight loss, or dysphagia. Because all procedures were carried out in a day endoscopy center, no patient had clinically significant pulmonary decompensation. The study did not differ significantly from routine gastroscopic procedure.

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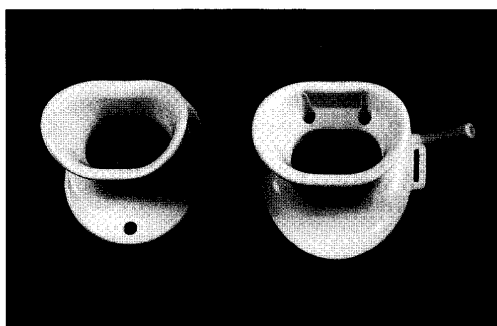
ture. All patients gave informed consent to take part in the study, which was conducted in accordance with the Declaration of Helsinki.<sup>7</sup>

### The Oxyguard

A new device, Oxyguard™ (Tri-Med Specialties, Overland Park, Kans.), was designed to deliver oxygen to the oral and nasal cavities during gastroscopy. By redesigning the standard plastic endoscopy mouthpiece, two tunnels were added to the device to deliver oxygen posteriorly into the oral cavity and two upwards toward the nose. Oxygen enters the Oxyguard™ via a side arm. In all other respects the device is similar in shape and size to a standard endoscopic mouthpiece (Fig. 1).

### Procedure and monitoring

After obtaining venous access and routine monitoring (blood pressure cuff), the patient's oxygen saturation was monitored using an Ohmeda Biox 3760 pulse oximeter with a finger probe. Between 1 and 5 min before the start of gastroscopy, the anesthetist administered an initial dose of either diazepam (2 to 5 mg) or midazolam (0.5 to 5 mg) and pethidine (0 to



**Figure 1.** The standard plastic endoscopic mouthguard is shown on the left. The novel oxygenating device (Oxyguard™) is of the same size and external shape, but with added posterior oxygenating tunnels (shown) and nasal tunnels (not visible). Oxygen is delivered to the Oxyguard™ via the side arm.

50 mg) intravenously, as clinically indicated. Lignocaine was applied to the patient's pharynx using five doses from a metered spray. The Oxyguard™ was inserted into the patient's mouth immediately following the lignocaine spray. Additional pethidine (25-mg increments) and diazepam (1 to 2 mg) or midazolam (0.5 mg) increments were used to reach adequate sedation. At this stage the patients were randomized to receive either supplemental oxygen 3 liters/min or to breathe room air. When the anesthetist was satisfied with the level of sedation, the endoscope was introduced. For each patient, the pulse oximeter produced a graphic printout of oxygen saturation and heart rate, with data recorded at 20-sec intervals.

In a second group of 21 patients scheduled to undergo endoscopy on two separate occasions, O<sub>2</sub> saturation (SaO<sub>2</sub>) was recorded with patients initially randomized to either Oxyguard™ (3 liters/min) or room air. For the subsequent endoscopy, the order was reversed. Patient sedation dose was identical on both occasions.

### Statistics

Statistical evaluation of the significance of the differences was made with the paired and non-paired Student's *t* test.

### RESULTS

One hundred twenty-four patients (69 women and 55 men) were studied with the Oxyguard™ and oxy-

genation, while 118 patients (53 women and 65 men) were studied using the standard mouthguard on room air. Full demographic data is included in Table 1. The mean (SEM) O<sub>2</sub> saturation rose significantly from a room air baseline of 92.5 (±0.2) to 95.4 (±0.2)% in patients given O<sub>2</sub> via the Oxyguard™. There was no such rise in those breathing room air. Following sedation and during endoscopy, the lowest recorded mean O<sub>2</sub> saturation fell in both groups to 86.5 (±0.5)% (room air) and 90.5 (±0.3)% (Oxyguard™). Averaged O<sub>2</sub> saturation for the entire procedure was 91.6 ± 0.3 (room air) vs. 95.4 ± 0.2 (Oxyguard™). The fall in O<sub>2</sub> saturation was significantly greater in those patients breathing room air (*p* < 0.001).

The distribution of mean O<sub>2</sub> saturation values in the 242 patients is shown in Table 2. Significant O<sub>2</sub> desaturation (SaO<sub>2</sub> < 90%) occurred in 25% of patients on room air and in 3% on Oxyguard™. Five percent of patients on room air had severe arterial oxygen desaturation (SaO<sub>2</sub> < 85%), while this did not occur in any patient using the Oxyguard™. Use of the oxygenating mouthguard reduced by more than 85% the number of patients who developed significant O<sub>2</sub> desaturation and completely prevented severe O<sub>2</sub> desaturation.

In the group of 21 patients endoscoped on two occasions with identical sedation doses, O<sub>2</sub> saturation was uniformly higher in the graphs of all patients using the Oxyguard™. Mean average O<sub>2</sub> saturation using the Oxyguard™ was 95.5 ± 0.6% and was significantly higher than that on room air of 91.7 ± 0.8% (*p* < 0.0005). The lowest mean O<sub>2</sub> saturation reached on Oxyguard™ was 90.5 ± 0.65% vs. 86.8 ± 1.4% on room air (*p* < 0.01, Fig. 2).

As the overall size and shape of the Oxyguard™ is no different from the standard endoscopic mouthpiece, the patients had no difficulty in using the device. The management of the Oxyguard™ by the anesthetist

**Table 2.**  
Distribution of oxygen saturations

Oxygen saturation (%)	% of patients	
	Room air (N = 118)	With Oxyguard™ (N = 124)
95-100	25	71
90-94	50	26
85-89	20	3
80-84	5	0

**Table 1.**  
Demographic data for patient groups

	N	M/F	Age (mean ± SD)	Smokers	Broad endoscopic diagnoses <sup>a</sup>				Associated diseases <sup>a</sup>	
					Duodenal ulcer	Gastric ulcer	Non-ulcer dyspepsia	Esophagitis	Asthma	Cardiovascular disease
Oxyguard™	124	55/69	52.2 ± 16.8	38/124	28	7	70	28	7	9
Room air	118	65/53	48.1 ± 16.6	34/118	29	6	59	29	7	12

<sup>a</sup> More than one diagnosis possible per patient.

was uncomplicated and no different from that of the standard mouthpiece.

Expenses involved in the use of the Oxyguard™ include the cost of the mouthguard and oxygen use. It is assumed the endoscopist uses on average five Oxyguards™ per 6 months, at approximately \$15.00/unit, giving a cost of 4.5¢ per patient and with an oxygen cost of 15¢ per patient.

In comparison, equivalent standard mouthguards costing \$6.00 each give an average cost of 2¢ per patient. However, for equivalent patient care, one would need continuous administration of oxygen via nasal cannulas. These may be less effective in the high proportion of patients who mouth-breathe under sedation.<sup>8</sup> Furthermore, nasal cannulas are generally discarded and not reused. At a cost of approximately \$2.00 per unit, plus oxygen (15¢ per patient), this form of oxygenation becomes comparatively more expensive. In effect, total costs of using standard mouthguards and disposable nasal cannulas amount to \$2.17 per patient, as compared with the Oxyguard™ cost of 19.5¢ per patient. All costs were based on listed prices in Sydney, Australia.

## DISCUSSION

Supplemental oxygen significantly improved O<sub>2</sub> saturation levels in our group of patients. This was evident whether average or minimal O<sub>2</sub> saturation values were compared. The effect was most noticeable in the groups reaching significant (SaO<sub>2</sub> < 90%) and severe hypoxemia (SaO<sub>2</sub> < 85%). The use of the oxygenating mouthguard prevented severe hypoxemia in all patients who otherwise would have been expected to desaturate below 85%. It is this group of patients, which is likely to be most susceptible to cardiopul-

monary complications,<sup>9,10</sup> that will benefit most from oxygenation.

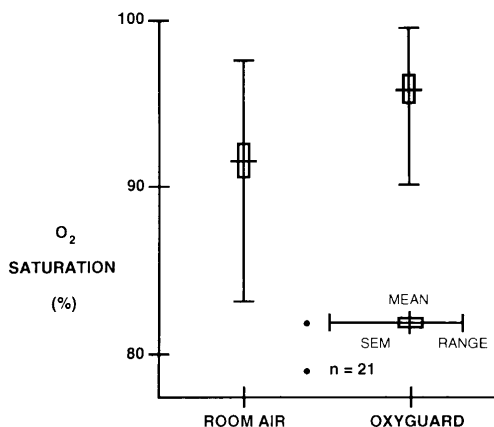
The Oxyguard™ (O<sub>2</sub> 3 liters/min) alleviates hypoxemia during gastroscopy in a manner which is similar to oxygenation using nasal prongs.<sup>5,6</sup> However, use of the oxygenating mouthguard simplifies the procedure by reducing the complexity of equipment attached to the patient. Furthermore, insertion of the oxygenating device becomes an automatic part of the endoscopic procedure, equivalent to the insertion of the plastic mouthpiece. Because nasal prongs deliver the oxygen only to the nose while the Oxyguard™ delivers oxygen to the mouth as well as the nose, it oxygenates nose and mouth-breathing patients.

Although the administration of oxygen via the Oxyguard™ significantly reduced the frequency of hypoxemia, it did not entirely eliminate the risk as has been shown with use of nasal prongs.<sup>11</sup> Hence, continuous monitoring of arterial oxygen saturation should still be used during gastroscopy, so that, in the event of severe desaturation corrective measures can be instituted to circumvent potentially serious complications.<sup>12</sup> Fortunately, use of nasal prongs<sup>5</sup> or the oxygenating mouthguard will prevent the majority of severe hypoxemic episodes.

If indeed provision of supplemental oxygen does reduce the frequency of cardiac arrhythmias, its use would be expected to benefit particularly the elderly or those patients with cardiovascular disease. The oxygenating mouthguard appears to be a simple yet effective method to deliver supplemental oxygen and alleviate hypoxia during gastroscopy.

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**Figure 2.** Oxygen saturation levels in 21 patients undergoing gastroscopy on separate occasions breathing either room air or oxygen via the Oxyguard™ (3 liters/min). Mean average O<sub>2</sub> saturation was higher with the Oxyguard™ ( $p < 0.0005$ ), and the lowest mean O<sub>2</sub> saturation was also significantly higher with the Oxyguard™ ( $p < 0.01$ ).