

Injury and Liability Associated with Monitored Anesthesia Care

A Closed Claims Analysis

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Background: To assess the patterns of injury and liability associated with monitored anesthesia care (MAC) compared with general and regional anesthesia, the authors reviewed closed malpractice claims in the American Society of Anesthesiologists Closed Claims Database since 1990.

Methods: All surgical anesthesia claims associated with MAC (n = 121) were compared with those associated with general (n = 1,519) and regional (n = 312) anesthesia. A detailed analysis of MAC claims was performed to identify causative mechanisms and liability patterns.

Results: MAC claims involved older and sicker patients compared with general anesthesia claims ($P < 0.025$), often undergoing elective eye surgery (21%) or facial plastic surgery (26%). More than 40% of claims associated with MAC involved death or permanent brain damage, similar to general anesthesia claims. In contrast, the proportion of regional anesthesia claims with death or permanent brain damage was less ($P < 0.01$). Respiratory depression, after absolute or relative overdose of sedative or opioid drugs, was the most common (21%, n = 25) specific damaging mechanism in MAC claims. Nearly half of these claims were judged as preventable by better monitoring, including capnography, improved vigilance, or audible alarms. On-the-patient operating room fires, from the use of electrocautery, in the presence of supplemental oxygen during facial surgery, resulted in burn injuries in 20 MAC claims (17%).

This article is accompanied by an Editorial View. Please see: Hug CC Jr: MAC should stand for maximum anesthesia caution, not minimal anesthesiology care. *ANESTHESIOLOGY* 2006; 104:221-3.

Conclusions: Oversedation leading to respiratory depression was an important mechanism of patient injuries during MAC. Appropriate use of monitoring, vigilance, and early resuscitation could have prevented many of these injuries. Awareness and avoidance of the fire triad (oxidizer, fuel, and ignition source) is essential to prevent on-the-patient fires.

THE use of monitored anesthesia care (MAC) as the technique of choice for a variety of invasive or noninvasive procedures is increasing.¹ Potentially serious complications in association with MAC have been described,²⁻⁸ but large prospective studies looking at the safety of MAC are lacking. Serious cardiorespiratory depression and death have been reported after sedation for diagnostic or therapeutic procedures in both adults and children.^{7,9} Polypharmacy of sedative-analgesic drugs,¹⁰ medication errors,¹⁰ inadequate monitoring of physiologic parameters,⁹ and delayed or inadequate resuscitation⁹ contribute to serious injury during sedation. We used the American Society of Anesthesiologists (ASA) Closed Claims database to compare closed malpractice claims for surgical anesthesia associated with MAC with those associated with general anesthesia (GA) and regional anesthesia (RA) since 1990.

Materials and Methods

General Description

The ASA Closed Claims Project is a structured evaluation of adverse anesthetic outcomes obtained from the closed claim files of 35 US professional liability insurance companies. Claims for dental damage are not included in the database.

The data collection process has been previously described in detail.¹¹⁻¹³ Briefly, a closed claim file was reviewed by a practicing anesthesiologist and typically consisted of relevant hospital and medical records; narrative statements from involved healthcare personnel; expert and peer reviews; summaries of depositions from plaintiffs, defendants, and expert witnesses; outcome reports; and the cost of settlement or jury award. The reviewer completed a standardized form that recorded information about patient characteristics, surgical procedures, sequence and location of events, critical incidents, clinical manifestations of injury, standard of care, and outcome.

The physical or psychological injury for which the

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patient was seeking compensation was recorded in each claim. In some claims, there was no apparent injury. Some claims had multiple injuries. In case of brain damage followed by death, death was considered the complication. Each claim was assigned a severity of injury score that was designated by the on-site reviewer using the insurance industry's 10-point scale that rates severity of injury from 0 (no injury) to 9 (death). For purposes of analysis, injuries were grouped into three categories: temporary-nondisabling (score = 0–5), disabling-permanent (score = 6–8), and death (score = 9). Patient injuries were judged for theoretical preventability by the on-site reviewer by the use of additional monitoring techniques, such as pulse oximetry and capnography, assuming optimal use of these techniques. Appropriateness of anesthesia care was rated as standard (appropriate), substandard, or impossible to judge by the reviewing anesthesiologists based on reasonable or prudent practice at the time of the event. The reliability of reviewer judgments previously has been found to be acceptable.¹²

Inclusion criteria for the current study were all surgical anesthesia claims in the ASA Closed Claims database originating in 1990 and later and collected through December 2002. Claims for obstetric care or pain management were excluded, as were claims in which the decade of origin of the claim was unknown. Claims in which no anesthetic was administered, the anesthetic technique was unknown, or a combined general plus regional technique was used were not included in the analysis.

Claims were classified as associated with MAC (*MAC claims*), associated with general anesthesia (*GA claims*) or associated with regional anesthesia (*RA claims*). Claims involving eye blocks (retrobulbar or peribulbar) were classified according to the nature of anesthesia care provided: If a surgeon performed the eye block and the anesthesiologist provided monitoring and sedation, the claim was classified as MAC; if the anesthesiologist performed the block, it was classified as RA. The primary damaging event (the primary mechanism causing the injury) was classified by the on-site reviewer and reviewed by the Closed Claims Committee. In addition, all MAC claims in which the primary damaging event was respiratory or medication related were reviewed by three of the authors (S. M. B., K. L. P., and K. B. D.) to assess the contributory role of sedation to the primary damaging event. Claims in which all three authors agreed that relative or absolute oversedation precipitated the cascade of events leading to the injury were grouped for in-depth analysis.

Statistical Analysis

Patient demographics, the damaging event, severity of injury, preventability by additional monitoring, standard of care, and frequency and amount of payment to the

plaintiff of MAC claims were compared with GA claims and RA claims. Mean ages were compared using the *t* test. Differences between proportions were evaluated using chi-square analysis, the Fisher exact test, and the Z test. A Bonferroni correction was used to correct for multiple comparisons (MAC *vs.* GA and MAC *vs.* RA), so $P < 0.025$ was required for statistical significance.

Payments for settlement and jury award were expressed in dollar amounts adjusted to 1999 dollars using the Consumer Price Index. Because payment did not exhibit a normal distribution, the median and range were used for descriptive purposes. Statistical comparisons of payment distributions were made using the Kolmogorov-Smirnov test. $P < 0.025$ was required for statistical significance.

Results

Comparison of MAC Claims to GA and RA Claims

Of 1,952 claims for surgical anesthesia in the analysis, 121 claims (6%) were associated with MAC, 1,519 (78%) were associated with GA, and 312 (16%) were associated with RA. MAC claims involved a higher proportion of patients aged older than 70 yr as compared with GA claims, and a higher proportion of ASA physical status III–V as compared with GA and RA claims ($P < 0.025$; table 1). One fifth of MAC claims occurred during eye surgery, and one fifth occurred during reconstructive or plastic surgical procedures in the head and neck areas, in contrast to GA ($P < 0.025$) or RA claims ($P < 0.025$ for head and neck procedures; table 1).

The severity of injury for MAC claims was similar to that for GA claims, with a similar proportion of death and permanent brain damage (fig. 1). Death and permanent brain damage were more common ($P < 0.01$) and temporary injuries were less common in MAC claims compared with RA claims ($P < 0.01$; fig. 1).

A respiratory damaging event led to an adverse outcome in similar proportions of MAC and GA claims but a significantly smaller proportion of RA claims ($P < 0.025$; table 2). Inadequate oxygenation/ventilation was the most common specific respiratory damaging event in MAC claims (table 2). Equipment-related damaging events also occurred more commonly in MAC claims than in RA claims ($P < 0.025$; table 2). Cautery fires were the most common equipment problem in MAC claims (table 2). These are described in more detail below. Inadequate anesthesia or patient movement during surgery was the primary damaging event responsible for 11% of MAC claims but only 3% of GA claims and 2% of RA claims ($P < 0.025$; table 2). Most MAC claims (83%) associated with inadequate anesthesia or patient movement resulted in eye injury during eye surgery or eye block administration. All eye surgery procedures were short in duration (cataract [$n = 24$], strabismus [$n = 1$]). Medication-related MAC claims included administration

Table 1. Patient and Case Characteristics

	MAC (n = 121), n (%)	GA (n = 1,519), n (%)	RA (n = 312), n (%)
Age, yr			
Mean age \pm SD	55 \pm 19*	44 \pm 20*	55 \pm 17
> 70 yr	31 (26%)*	150 (10%)*	71 (23%)
< 16 yr	1 (1%)*	140 (9%)*	2 (1%)
Sex			
Female	76 (63%)*†	776 (52%)*	150 (48%)*†
Male	44 (37%)*†	730 (48%)*	161 (52%)*†
ASA physical status			
I, II	48 (48%)*†	735 (59%)*	164 (67%)*†
III–V	53 (52%)*†	504 (41%)*	79 (33%)*†
Emergent procedure			
Emergent	9 (8%)*	228 (17%)*	26 (9%)
Elective	99 (92%)*	1145 (83%)*	258 (91%)
Outpatient/inpatient			
Outpatient	83 (74%)*†	377 (27%)*	142 (51%)*†
Inpatient	29 (26%)*†	1004 (73%)*	137 (49%)*†
Surgical procedure			
Eye surgery	25 (21%)*	25 (2%)*	45 (14%)
Head, neck, or face repair or superficial biopsy	23 (19%)*†	69 (5%)*	4 (1%)*†
Endoscopy	9 (7%)*	20 (1%)*	10 (3%)

Percentages are based on claims without missing data.

* $P < 0.025$ monitored anesthesia care (MAC) vs. general anesthesia (GA) claims. † $P < 0.025$ MAC vs. regional anesthesia (RA) claims.

ASA = American Society of Anesthesiologists.

of the wrong drug or dose and adverse drug reactions (9%). Examples of medication-related injuries included unexpected neuromuscular blockade while awake after mistaken administration of vecuronium; anaphylaxis after administration of ketorolac to a patient with an aspirin allergy; infection after contaminated propofol; and agitation, vomiting, or excessive sedation after opioids or sedative agents.

The standard of care was judged by reviewers to be

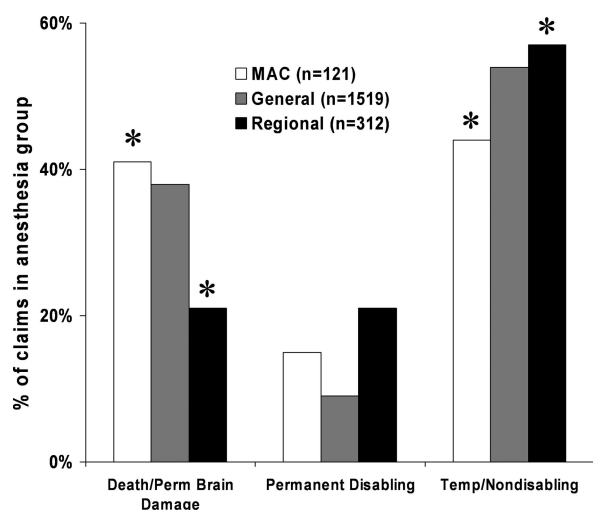


Fig. 1. Severity of injury in monitored anesthesia care (MAC), general, and regional anesthesia claims. The proportion of claims for death (14%) and permanent brain damage (7%) was reduced in regional anesthesia compared with MAC (33% death and 8% brain damage). In contrast, the severity of injury was similar between MAC claims and those associated with general anesthesia (27% death and 10% brain damage). * $P < 0.025$ MAC versus regional.

appropriate in 59% of MAC claims, no different from GA claims but significantly less than from RA claims (74%, $P < 0.025$; table 3). However, the proportion of claims where payment was made to the plaintiff and the payment amounts were similar in the three types of anesthetic care (table 3).

Oversedation Leading to Respiratory Depression

Respiratory depression due to an absolute or relative overdose of sedative-hypnotic-analgesic agents was responsible for 25 MAC-related claims (21%) (table 4). Six claims (24%) related to sedation occurred during MAC for endoscopic procedures (table 4). Propofol was used in half of the cases, either alone ($n = 2$) or in combination with a benzodiazepine and/or an opioid ($n = 11$; table 4). A combination of benzodiazepine and opioid was used in 7 cases (table 4). Death or brain damage resulted in most of the claims related to oversedation (table 4). The anesthesia care was judged to be substandard in most of these claims (table 4). Although most had pulse oximetry in use and 20% had both pulse oximetry and capnography in use at the time of the event, nearly half of the claims were judged as preventable by additional (or better) monitoring (table 4). Distraction due to loud music in the operating room ($n = 1$), inattention to the monitors ($n = 4$), monitor alarms off ($n = 2$), poorly functioning pulse oximeters in sick patients ($n = 3$), delay in resuscitation due to prone position ($n = 6$) or being in the magnetic resonance imaging scanner ($n = 2$), and poor resuscitation ($n = 2$) contributed to adverse outcomes. The median payment for claims related to oversedation was \$254,000 (table 4).

Table 2. Mechanisms of Injury

	MAC (n = 121), n (%)	GA (n = 1,519), n (%)	RA (n = 312), n (%)
Respiratory event	29 (24%)†	337 (22%)	11 (4%)†
Inadequate oxygenation/ventilation	22 (18%)*†	33 (2%)*	5 (2%)†
Cardiovascular event	17 (14%)	253 (17%)	23 (7%)
Equipment failure/malfunction	25 (21%)†	199 (13%)	8 (3%)†
Cautery fires	20 (17%)*†	10 (1%)*	1 (0%)†
Related to regional block	2 (2%)†	7 (0%)	168 (54%)†
Inadequate anesthesia/patient movement	13 (11%)*†	42 (3%)*	7 (2%)†
Medication related	11 (9%)	95 (6%)	11 (4%)
Other events‡	24 (20%)*	586 (39%)*	84 (27%)

* $P < 0.025$ monitored anesthesia care (MAC) vs. general anesthesia (GA) claims. † $P < 0.025$ MAC vs. regional anesthesia (RA) claims. ‡ Other events includes surgical technique/patient condition, patient fell, wrong operation/location, positioning, failure to diagnose, other known damages, no damaging event, and unknown.

Burn Injuries after Fires

Burns, particularly involving the head or neck, were another important type of injury during MAC (n = 20; table 5). An electrocautery (diathermy) unit was responsible for the ignition in all cases. Supplemental oxygen using a facemask or nasal prongs was being used in all cases at various flow rates (table 5). Alcoholic prep solution (n = 5, 31%) and drapes (n = 13, 81%) were the most common sources of fuel. Payment to plaintiff was made in 89% of these cases, with a median payment of \$71,375 (table 5).

Discussion

The severity of injury for MAC claims was comparable to GA claims, with 41% of the claims being for death or permanent brain damage. Respiratory depression as a result of oversedation was the most common mechanism of injury. Burns associated with the use of supplemental oxygen in proximity to an electrocautery was also a major source of injury.

Limitations of Closed Claims Analysis

The limitations of analyzing and interpreting the data gathered from the ASA Closed Claims Project Database have been previously described.^{13,14} Foremost, the database does not have data on the total number of adverse

outcomes (the numerator) or the total number of anesthetics performed (the denominator), thus making it impossible to provide any numerical estimates of the risks associated with MAC. Only a minority of adverse events result in a malpractice claim.¹⁵ Second, the data are collected in a nonrandom, retrospective manner from direct participants. Third, the database has only that information which the reviewer could obtain from the insurance company files. Incompleteness of specific detailed information regarding the sequence of events or mechanism of injury makes closed claims analysis weaker than prospectively collected data.

Oversedation during MAC

Our review found nearly 75% of the patients who experienced injury related to sedation received a combination of two or more drugs, either a benzodiazepine and an opioid or propofol plus others. Bailey *et al.*¹⁶ observed that a combination of midazolam and fentanyl significantly increased the incidence of hypoxemia and apnea in volunteers, as compared with either of the drugs alone. Additive or even synergistic effects on depression of ventilatory response to carbon dioxide have been demonstrated when remifentanyl and propofol¹⁷, alfentanil and propofol,¹⁸ or alfentanil and midazolam¹⁹ were combined. Serious cardiorespiratory depression after a combination of an opioid and a benzodiazepine has

Table 3. Standard of Care and Payment

	MAC (n = 121), n (%)	GA (n = 1,519), n (%)	RA (n = 312), n (%)
Standard of care			
Standard	61 (59%)*	845 (64%)	201 (74%)*
Substandard	43 (41%)*	470 (36%)	69 (26%)*
Payment to plaintiff			
Payment made	57 (51%)	716 (52%)	131 (47%)
Median payment	\$159,000	\$140,000	\$127,000
Range of payments	\$8,175–2,167,009	\$95–17,934,000	\$832–6,360,000

Percentages are based on claims without missing data. Payments were adjusted to 1999 dollars using the Consumer Price Index. Claims with unknown year of event were excluded.

* $P \leq 0.025$ monitored anesthesia care (MAC) vs. regional anesthesia (RA) claims.

GA = general anesthesia.

Table 4. Characteristics of MAC Claims Associated Oversedation (n = 25)

Characteristic	n (%)
Aged 70 yr or older (n = 24)	10 (42)
ASA PS III–V (n = 22)	10 (45)
Obese (n = 18)	6 (33)
Endoscopy (n = 25)	6 (24)
Sedative agents (where known) (n = 22)	
Propofol alone	2 (9)
Propofol plus others	11 (50)
Benzodiazepine + opioid	7 (32)
Benzodiazepine or opioid alone	2 (9)
Monitoring in use (n = 25)	
Pulse oximetry only	17 (68)
Both pulse oximetry and capnography	5 (20)
Neither	3 (12)
Preventable by better monitoring (n = 25)	11 (44)
Pulse oximetry	3 (12)
Capnography	5 (20)
Both	1 (4)
Death or permanent brain damage (n = 25)	21 (84)
Substandard care (n = 23)	18 (78)
Payment to plaintiff	
Payment made (n = 20)	10 (50%)
Median (range) of payments (n = 10)	\$254,000 (\$72,800–2,080,000)

Percentages are based on claims without missing data. Denominators are listed in parentheses. Payments were adjusted to 1999 dollars using the Consumer Price Index.

ASA PS = American Society of Anesthesiologists physical status.

also been reported by Arrowsmith *et al.*⁷ Depression of hypoxic ventilatory drive by benzodiazepines,^{20,21} opiates,²² or propofol,²³ and blunting of ventilatory response to carbon dioxide by opioids²⁴ and benzodiazepines²⁵ results in significant hypoventilation.

Noxious stimulation is a “natural antagonist” to respiratory depression by opioids and other sedative agents. Respiratory depression may become evident after the noxious stimulation ceases or decreases in intensity. Propofol may exert a greater synergistic effect with opioids as compared with nitrous oxide with opioids, because considerably lower concentrations of alfentanil were required as a supplement to propofol as compared with supplementation during nitrous oxide anesthesia.²⁶ Therefore, smaller doses and greater caution are advised with administration of combinations of propofol, benzodiazepines, and opioids. A combination of two or more drugs for sedation for outpatient procedures has been found to be relatively safe in many studies.^{27,28} However, these patients were relatively young and healthy (mostly

Table 5. Characteristics of MAC Claims Resulting in Burns after Electrocautery (n = 20)

Characteristic	n (%)
Aged 70 yr or older (n = 20)	7 (35)
ASA PS III–V (n = 16)	3 (19)
Head, neck, face, or biopsy* (n = 20)	19 (95)
Oxygen administration device (n = 19)	
Facemask	7 (37)
Nasal prongs	9 (47)
Unknown device	3 (16)
Oxygen flow rate, l/min (n = 9)	
< 5	5 (56)
≥ 5	4 (44)
Fuel† (n = 16)	
Drapes	13 (81)
Alcoholic prep solutions	5 (31)
Facial hair	1 (6)
Substandard care, % (n = 14)	7 (50)
Payment to plaintiff, % (n = 18)	16 (89)
Median (range of payments) (n = 16)	\$71,375 (\$8,175–321,323)

Percentages are based on claims without missing data. Denominators are listed in parentheses. Payments were adjusted to 1999 dollars using the Consumer Price Index.

* Only one procedure was not located on the head, neck, or face. It was removal of arm lesions. † Fuel was unknown in four claims. In three claims, alcohol and drapes were ignited.

ASA PS = American Society of Anesthesiologists physical status.

ASA physical status I or II). Half of the patients who were oversedated in our review were elderly or had an ASA physical status of III–V and hence were probably more susceptible to the respiratory depressant effects of the sedative-analgesic-hypnotic drugs used. Titration to effect by very slow administration of sedatives and opioids may be important to avoid respiratory depression in this patient population.

Monitoring during MAC

Nearly half of the injuries related to sedation in our closed claims review were judged as preventable by the use of additional or better monitoring. The ASA Standards for Basic Anesthetic Monitoring mandate that the adequacy of ventilation be evaluated during MAC by continual observation of qualitative clinical signs and/or monitoring for the presence of exhaled carbon dioxide.²⁹ Although continuous capnography is required for all patients undergoing general anesthesia, it is optional for MAC cases. Precordial or esophageal stethoscope, capnography, or electrical impedance monitoring can be used for a continuous monitoring of ventilation and inspired oxygen, and pulse oximetry can be used to monitor the oxygenation. Apnea lasting 20 s or more is common in patients undergoing MAC and is not easily detected by the providers without the use of capnography or electrical impedance monitoring.²⁹ Detection of apnea or hypoventilation may be delayed in patients receiving supplemental oxygen during MAC.^{30,31} Our closed claims analysis suggests that patient safety during MAC may be improved by the use of capnography or

** Standards for Basic Anesthetic Monitoring (Approved by ASA House of Delegates on October 21, 1986, and last amended on October 27, 2004). Available at: <http://www.asahq.org/publicationsAndServices/standards/02.pdf#2>. Accessed July 12, 2005.

other continuous monitors of ventilation. However, the reliability of capnography as a respiratory monitor during MAC is affected by oxygen fresh gas flow rate, tidal volume, and the location of the monitor in relation to breathing pattern. False information may also be derived from monitoring thoracic impedance in the presence of airway obstruction.

Lack of vigilance contributed to damage in many of the events. The national patient safety goals of the Joint Commission on Accreditation of Healthcare Organizations recommends activation of alarms with appropriate settings and sufficiently audible with respect to distances and competing noise within the unit.^{††} The Anesthesia Patient Safety Foundation also stresses use of audible monitor alarms, including pulse oximetry and at least one other physiologic monitor.³² Audible alarms reduced the severity of injury in 58 anesthetic incidents reported in the United Kingdom.³³ Vigilance by the anesthesiologist is needed to take prompt action on the physiologic parameter(s) that have been deranged. Delay in resuscitation, despite the warning from an alarm system, and poor resuscitation led to injury in our review.

The implications of our closed claims review for the practice of anesthesia are that MAC providers need to be aware of the risk of serious respiratory depression when sedative-analgesic-hypnotic medications are used in combination, especially in elderly patients or those with systemic diseases. Continuous monitoring of ventilation and oxygenation, with audible alarms, and constant vigilance are mandatory.

Burn Injuries during MAC

Burns, particularly involving the head and neck, were surprisingly important injuries associated with MAC. On-the-patient operating room fires result when the triad of an oxidizer (such as oxygen or nitrous oxide), a combustible substance (such as paper drapes, alcohol-based prep solutions, plastic masks, or hair), and a source of ignition (such as an electrosurgical unit) are all simultaneously present.³⁴⁻³⁷ The proximity of supplemental oxygen to the surgical site during head and neck surgery increases the possibility of surgical fire during the use of electrocautery, especially when a "tent of drapes" around the patient's face allows the buildup of higher concentrations of oxygen.³⁵ Open face draping technique, administration of supplemental oxygen at the lowest acceptable flow rates only when indicated by pulse oximetry value, use of compressed air instead of oxygen to prevent buildup of carbon dioxide, stopping oxygen flow 60 s before the use of the electrocautery, avoidance of alcohol-based prep solutions, and aware-

ness of the causation of surgical fire can help to minimize the incidence of on-patient fires.^{34,36,37}

Claim Payments

Payment frequency and amounts were similar for all types of anesthesia. Payment frequency reflects primarily standard of care, with higher proportions of payment for substandard care.¹³ Payment amount reflects both standard of care and severity of injury, as well as age, sex, and general health for calculation of economic damages.¹³ Payments for death are lower than for disabling injuries that require long-term care.¹³ Similar payment amounts for RA compared with MAC and GA, despite a lower proportion of death and brain damage, may reflect serious nerve, especially spinal cord, injuries associated with RA.

Summary

Claims associated with MAC showed a high severity of patient injury and a liability profile similar to claims associated with general anesthesia. The most common sources of injury during MAC were severe respiratory depression resulting in death or brain damage associated with drugs used for sedation, and burn injuries from fires caused by the electrocautery in the presence of supplemental oxygen.

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