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MCSLEEPY ADVANCES

Automated Anesthesia and Natural Orifice Transuluminal Endoscopic Surgery

by **Douglas J Hughes**, CST, CSFA, CSA, CRCST

As the world moves further into a future booming with technological advances and scientific discoveries, many aspects of society will be directly impacted and potentially enhanced in groundbreaking ways. Few areas or fields of practice have experienced these advancements with as much fervor as healthcare and medicine. Throughout the history of medical practice, technological advances have had dramatic impacts on such aspects as the delivery of care, the discovery of disease and the treatment of a myriad of conditions and illnesses. Today, several new technologies are emerging on the horizon and each carries the potential to fundamentally change modern healthcare and medical sciences yet again. Two specific examples of interest are automated, closed-loop anesthesia systems and natural orifice transluminal endoscopic surgery.

AUTOMATED, CLOSED-LOOP ANESTHESIA SYSTEMS: MCSLEEPY

More than 150 years ago, Boston dentist, William TG Morton, and renowned surgeon John Collins Warren, MD, worked together to pioneer and demonstrate the first-ever painless surgery using general anesthesia administered in the form of ether. After successfully removing a vascular tumor from the jaw of a patient named Gilbert Abbott at Massachusetts General Hospital in 1846, the two ushered in a new era in surgical medicine and laid the foundation for modern operative intervention aided by the administration of anesthetic agents.[9] Since that time, the use of general anesthe-

John Collins Warren, MD

William TG Morton

LEARNING OBJECTIVES

- Define natural orifice transluminal endoscopic surgery
- Examine automated, closed-loop anesthesia systems
- Explore McSleepy and the revolution of robotic systems in the operation room
- Examine how robotic systems will advance the future of surgical procedures
- Assess the current and future states of NOTES

Thomas M Hemmerling, MD, works with McSleepy, the first fully-automated anesthesia robot.

sia has become highly refined, sophisticated and routine. As researchers and practitioners alike continue to explore and implement safer and more efficient methods for administering and monitoring intraoperative anesthesia to control pain, induce muscle relaxation, and maintain patient hypnosis and unconsciousness, new advanced technologies are surfacing with increasing fervor.[8] Perhaps the most revolutionary advancement in modern anesthesia science since Morton and Warren successfully conquered operative pain is currently being trialed at McGill University Health Centre in Montreal, Canada. This new technological marvel, dubbed "McSleepy" by its creators, is a highly advanced, automated, robotic system capable of administering and maintaining anesthesia more safely and efficiently than a living, breathing anesthetist.[11]

ANESTHESIA MONITORING AND AUTOMATION

Since the early days of ether use, a fundamental problem related to the art of anesthesia delivery and maintenance has remained. Despite the many advances in intraoperative patient monitoring and the discovery of more sophisticated and safer drugs, there is still a great deal of subjectivity that exists in knowing when the correct amount of anesthetic agent has been given to the patient to produce the desired level of effectiveness while maintaining adequate homeostasis.[6] As early as the late 1940s and 1950s, experimenters such as Reginald Bickford, MD, used the electroencephalogram (EEG) — and recently the bispectral index (BIS) — as a method of monitoring the relationship between the amounts of anesthetic administered to the patient and the subsequent level of unconsciousness attained. The advent of such technologies made it possible for researchers and practitioners in anesthesiology to control at least one aspect of anesthetic drug administration and ultimately automate it in order to reduce the amount of subjectivity related to dosage and titration.[5,6] This type of automation was developed in the form of closed-loop anesthesia systems.

CLOSED-LOOP ANESTHESIA DELIVERY SYSTEMS

Closed-loop anesthesia systems utilize complex algorithms based on patient data such as BIS monitoring, initial drug dosage, pharmacokinetics, pharmacodynamics and other biological factors to calculate and administer the appropriate intraoperative anesthesia dosage for each surgical patient. Such systems have been known for the administration and dosage of intravenous propofol for several years, although their acceptance in the clinical setting has been slow to mature due to limited reliability and safety because of a lack of robust patient monitoring technology. Glass[5] referred to a study by Struys et al that noted that such systems, while still in their clinical infancy, showed great potential and provided better hemodynamic control and faster patient recovery under ideal conditions than manual administration of propofol via a human anesthetist alone. However, the variability in biology between patients and the difficulty in monitoring various physiologic and pharmacokinetic aspects of anesthesia during automated administration has limited the usefulness of such closed-loop systems until recently. Since these earlier studies only a decade ago, Glass[5] states that current technological advances in patient monitoring and algorithmic pharmacology have lead to better control over patient-specific biological factors and subsequently to the development of more robust closed-loop systems capable of more comprehensive intraoperative duties. Although he contends that these systems have a long way to go before they replace human practitioners, the idea of clinically-viable automated anesthesia administration is no longer a matter of science fiction.[6,10] No better example of this exists today than the advances made at McGill University during the last couple of years.

MCSLEEPY: THE FIRST FULLY-AUTOMATED ANESTHESIA ROBOT

In early 2008, the world's first fully-automated anesthesia system — McSleepy — was successfully tested during a 3½-hour partial nephrectomy procedure at McGill University Health Centre in Montreal. Using advanced closed-loop anesthesia technology and highly sophisticated patient monitoring techniques and algorithms, McSleepy is capable of performing anesthesia administration and maintenance for an entire surgical procedure with limited human oversight.[13] When describing the technology, Thomas M Hemmerling, MD, the lead researcher for the project, stated, "Think of McSleepy as a sort of humanoid anesthesiologist that thinks like an anesthesiologist, analyses biological information and constantly adapts its own behavior, even recognizing monitoring malfunction."[11]

Commonly referred to as an anesthesia robot, McSleepy monitors the patient's level of consciousness, pain and muscle movement throughout the course of the surgery and adjusts the level and dosage of intravenous agents accordingly. In order to facilitate its operation, the patient is connected to several advanced biological sensors and demographic information such as age, weight, height, sex and type of surgery to be performed is entered into the system. McSleepy also has the ability to store and learn surgeon and anesthesiologist-specific preferences through incorporated artificial intelligence technology. Every minute that the patient is under general anesthesia, McSleepy uses the mathematical algorithms of its closed-loop programming, via LabView-developed software, to monitor and dose the anesthetic agents. As a fail-safe in the event that McSleepy malfunctions, anesthesia providers are able to override the system and revert to manual control of anesthesia administration. The override feature also gives them the ability to alter doses as needed based on their individual preferences and observations.[8]

BENEFITS AND POTENTIAL IMPACT

In October 2010, the McSleepy anesthesia robot was combined with the DaVinci surgical robot to perform the world's first total-robotic operation. Utilizing these two systems together to perform a successful prostatectomy procedure on a MUHC patient, the event has begun a new chapter in the quest for less invasive, faster, safer and more accurate surgical interventions. Although researchers contend that some work still needs to be done to perfect the approach, there is little doubt that all-robotic surgical techniques will gain interest and eventual acceptance. In light of the recent press — and because the use of McSleepy has been shown by McGill researchers to lead to higher quality patient care, better intraoperative monitoring, and more accurate dosing and maintenance of anesthesia by eliminating the subjectivity of human clinicians — it is likely that the technology will stay.[12]

Along with the major benefits associated with advanced patient monitoring and more accurate dosing, several other advantages to using McSleepy in the clinical setting exist, thus lending it the potential to revolutionize patient care. The most obvious added advantage is the fact that using this system will free anesthesiologists from the time-consuming burden of monitoring, and managing the administration of intraoperative agents. According to Hemmerling,[8] anesthesia providers spend approximately 20% of their time engaged in these activities. Thus, they will be able to focus their time and energy on other important aspects of patient care. The decreased oversight may also lead to a 20% to 25% drop in total costs for anesthesia services, therefore making surgery more affordable to patients.[3]

Unlike other prototypes, McSleepy's program is loaded onto a laptop connected to monitors and infusion pumps and sports a user-friendly interface that is similar to that of current anesthesia delivery systems. This feature has led to a great deal of interest among clinicians as other concepts under development lack such an interface and are harder to program and use.[8,11] Because of this advantage, Hemmerling

"Think of McSleepy as a sort of humanoid anesthesiologist that thinks like an anesthesiologist, analyses biological information and constantly adapts its own behavior, even recognizing monitoring malfunction."

believes that patients will be less reluctant to rely on the system because it is more "visible" and reduces the fear of an unknown device or "black box" taking over.[11,13]

> Minimally-invasive approaches to operative access and exposure have served to greatly reduce the risks and complications associated with the creation of larger, more complicated wounds.

Another important advantage of McSleepy is its integration of Wi-Fi and mobile technology. The system gives the operator the ability to monitor the patient's progress and drug dosages from any location via a PDA.[3] The implications of this feature may prove to be astounding. Essentially, clinicians will be able to monitor several patients simultaneously via a remote or centralized location. All of the functions available through McSleepy's laptop interface are also accessible wirelessly. In the future, this may prove to be highly beneficial in countries that lack access to skilled anesthetists.[8]

THE FUTURE

Although Hemmerling recognizes that many patients initially will be skeptical of this new technology and prefer a human anesthesiologist at their side, he has been bold enough to state that McSleepy will enter the US market within the next five years. His team is currently preparing commercial versions of the automated anesthesia system and is actively involved in the approval process through both the US Food and Drug Administration and Canadian health agencies.[8] With clinical evidence showing that automated systems may in fact be better and more efficient than manual anesthesia administration alone — and considering the recent advances in patient monitoring paving the way for more viable closed-loop algorithmic anesthesia systems — Hemmerling is not alone in his optimism. Glass[6] stated, "I remain optimistic that closed-loop control of anesthesia ultimately will prove to be superior and will become routine in providing anesthesia." Although devices such as McSleepy and other surgical robots such as DaVinci stimulate the thought of replacing doctors with machines in the not-too-distant future, Hemmerling contends that, "Robots will not replace doctors, but help them to perform to the highest standards."[18] While this may be true for now, a future in which patients are routinely cared for and treated by robotic physicians is certainly on the horizon.

NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY

Throughout the history of surgical intervention, practitioners have continuously sought methods to achieve their desired operative outcomes while minimizing specific negative side effects such as large incisions, postoperative pain, lengthy recoveries and the risk of wound infection, to name a few. During the last two centuries, the advent of endoscopes and related technologies has played a central role in the genesis of modern therapeutic and diagnostic techniques. From Phillip Bozzini's development of the first crude endoscope in 1805, to the development of the first technique for laparoscopic removal of the gallbladder by the German surgeon Erich Mühe in 1985, the evolution of minimally-invasive methodologies has been dramatic and revolutionary.[20] Following this tradition, a new experimental approach, known as natural orifice transluminal endoscopic surgery, or NOTES, shows great potential to further alter the state of disease diagnosis and treatment in a fundamental way.

BENEFITS OF MINIMALLY-INVASIVE SURGERY

One of the most obvious commonalities shared by operative procedures across the various disciplines is the creation of the surgical wound or incision to gain access to and expose the operative field. Traditionally, such incisions have been performed through normal, intact, external structures such as the pelvis, flank and abdomen. As incisions are carried through superficial and deeper tissues such as the skin, subcutaneous fat, fascial layers, various musculatures and the peritoneum, the disruption of complex anatomic structures and physiologic systems is an inherent consequence. Therefore, the patient is subjected to complications in the form of postoperative pain, scarring, possible wound infection, incisional hernia and others.[16] Minimally-invasive approaches to operative access and exposure have served to greatly reduce the risks and complications associated with the creation of larger, more complicated wounds.[2] The current minimally-invasive laparoscopic revolution has greatly enhanced recovery of the surgical patient while simultaneously decreasing morbidity, postoperative pain, healing time, length of hospital stay and certain risks such as intestinal ileus and tissue adhesions when compared to traditional open laparotomy approaches. Also, the smaller incisions employed during laparoscopic techniques results in enhanced cosmesis and greater patient satisfaction.[1] Yet despite these numerous benefits, researchers and clinicians still are actively seeking further improvements. There are a growing number of surgeons who are looking for ways to not only minimize the size of incisions into the skin, but eliminate them altogether. Therefore, the recent developments in natural orifice transluminal endoscopic surgery offer the next potential revolution in minimally-invasive operative techniques.[19]

NOTES DEFINED

Reaching beyond the capabilities of even the most advanced laparoscopic systems available on the market today, NOTES utilizes the body's natural orifices to access internal abdominal organs and structures without leaving an external scar. The insertion of a highly sophisticated endoscope and advanced surgical instrumentation into external structures such as the mouth, urethra, anus or vagina will enable surgeons to perform operative procedures without the need to create even the smallest incision into the abdominal wall. The natural orifice approach holds tremendous potential to reduce patient complications and improve postoperative recovery time as the risks and side effects associated with abdominal incisions are completely eliminated.[2]

THE PROCEDURE

According to Yan and Thompson-Fawcett,[20] five approaches to NOTES peritoneal access have been identified. They include are transcolonic, transgastric, transvaginal, transvesical and a combined method. Selecting the desired point of entry into the body will depend largely on the area of the abdomen to be accessed as each route provides for visualization of different internal organs and separate portions of the abdominal cavity. In either of these approaches, the procedure involves the insertion of an endoscope through an overtube into the chosen orifice followed by the thorough suctioning of its contents and an antibiotic lavage. Additionally, bowel prep, water enemas, aggressive intraluminal washing and an external skin preparation with povidone iodine scrub solution may be necessary for transcolonic procedures. The endoscope used to prepare the operative site for the incision is then removed to reduce the presence of microbial flora, and another — with additional working channels — is introduced. A small viscerotomy or enterotomy is then created in the wall of the viscera or intestinal tract with a small instrument such as a 4-mm needle-knife delivered via the endoscope. The incision can then be enlarged using any of several different endoscopic instruments depending on the surgeon's preference. Commonly, a 1.5-cm pull-type sphincterotome, or balloon dilator is employed for expansion. Once this step is complete, the endoscope is advanced through the incision and into the peritoneal cavity, where the surgical intervention will take place.[14,19,20] Pneumoperitoneum is then achieved with carbon dioxide gas at an intraabdominal pressure not to exceed 15 mmHg.[20] Using standard endoscopic instrumentation, a number of surgical procedures can be performed. Once the procedure is complete, the viscerotomy is tightly closed using endoclips or a prototype closure device to prevent spillage of the visceral contents into the abdomen. Finally, the endoscope, surgical instrumentation and overtube are removed from the body orifice.[19]

An endoscopic surgery operation room.

THE CURRENT STATE OF NOTES RESEARCH

Following these basic operative steps, researchers have been able to trial the effectiveness of NOTES in a variety of surgical cases ranging from peritoneal endoscopy, to transvaginal cholecystectomy, to transgastric gastrojejunostomy and splenectomy.[19] This new "scarless" approach to operative and diagnostic therapy is a combination of both endoscopic and laparoscopic techniques and is currently in its experimental/developmental phase.[14] Much of the research has been conducted using animals such as canine and porcine models since Kalloo et al performed the first transgastric peritoneal exploration on a pig in 2004.[20] However, human trials have been conducted to a minimal extent and largely have been confined to transgastric appendectomies performed in Hyderabad, India, by GV Rao, MD, and Nageshwar Reddy, MD.[19] Data related to these human trials of NOTES technology are limited at best. The tremendous interest in this technology also has led to the performance of several hundred hybrid laparoscopic assisted NOTES procedures in Asia and the US, most commonly transvaginal procedures.[1] Overall, these cases have proven to be highly successful demonstrations of the potential for natural orifice surgery to revolutionize modern medicine and surgical practice.

CURRENT LIMITATIONS AND CHALLENGES

Although the operative procedure may seem straight forward, several limitations and challenges must be overcome before NOTES can be defused into mainstream surgical practice. The biggest hurdle in the way of this technology is the current lack of an effective closure device for the internal wall of the viscera. Many practitioners and researchers have opted to use endoclips for viscerotomy and enterotomy wound closure. However, these devices are intended for the maintenance of intraoperative hemostasis and are not adequate for primary tissue approximation as they are incapable of full-thickness tissue closure. Currently, devices are being prototyped to meet this emerging need.[19]

Another one of the critical drawbacks at this stage of development is the lack of adequate surgical instrumentation and equipment needed to facilitate fully transluminal procedures on human patients. Although many successful procedures have been performed on animal test subjects, human anatomical structure and tissue vary greatly from these species. Attaining the high level of clinical precision that is necessary to manipulate human tissue is not currently possible without more specialized endoscopic instruments.[2] Standard endoscopic instrumentation such as graspers, baskets, forceps, electrosurgical devices and scopes lack the flexibility requirements and degrees of freedom needed to carry out a safe and efficient NOTES operation.[1] Furthermore, several advances are needed to improve the field of visualization and overall functionality available in flexible endoscope models on the market.

> The concept of natural orifice transluminal endoscopic surgery promises to completely revolutionize modern surgical medicine by overcoming the many drawbacks that exist with current operational methods.

Currently, several companies are designing and testing prototype endoscopes, closure devices and endoscopic instrumentation to meet the specific demands of NOTES procedures. A myriad of new technological advances will reach the market during the next few years, effectively bridging the gap that exists between theory and practice.[1,7] In the meantime, natural orifice transluminal endoscopic surgery will have limited benefit to humans. However, experimentation with hybrid surgical approaches and research through animal trials will most certainly continue.

THE FUTURE

The concept of natural orifice transluminal endoscopic surgery promises to completely revolutionize modern surgical medicine by overcoming the many drawbacks that exist with current operational methods. As new NOTES technologies are developed and defused into practice, Forgione[4] contends that they will, "Lead to the design of completely new interventional procedures, and change the way we will operate, bringing us to the previously unimaginable goal of 'no-scar surgery.'"

Just what exactly will the future of NOTES look like? For one, the elimination of the abdominal incision and use of minimally-invasive endoscopic technology will allow needed procedures to be performed on patients that are not currently considered viable surgical candidates, such as ICU patients suffering from comorbid diseases, other illnesses or conditions and advanced age. The portability of this technology will even enable such procedures to be performed bedside in ICU and emergency department suites.[15] This factor alone carries the capacity to fundamentally change surgical principles and practices in a profound way. Also, substantial decreases in tissue trauma, operative pain, the time needed for dissection and exposure of the operative field, as well as the elimination of the need for abdominal muscle paralysis, will likely allow many NOTES procedures to be performed under conscious sedation rather than general anesthesia.[14,15] This advantage will greatly decrease postoperative recovery time and the risk of anesthetic complications. Furthermore, the fact that endoscope reprocessing utilizes high-level disinfection versus sterilization could make NOTES procedures appropriate for environments such as third-world countries and battlefields.[20] With all of these potential benefits, Song, Itawi, and Saber[17] believe that NOTES will soon make its debut in hospitals and specialty centers in the US. As the diffusion of this technology becomes a reality during the next decade, Chaudhry and Agrawal[2] point out that many levels of society will be directly impacted; specifically, hospitals and surgical centers, healthcare and insurance systems, government and legislative organizations and professional associations.

CONCLUSION

Automated, closed-loop anesthesia systems and natural orifice transluminal endoscopic surgery are two quickly emerging technologies that likely will have a drastic impact on healthcare and medical/surgical sciences during the next five to 10 years. Although currently under development, both are being evaluated as viable and effective alternatives to modern systems and techniques. These futuristic advancements already have sparked worldwide interest and promise to revolutionize both the healthcare industry and society alike.

ABOUT THE AUTHOR

Douglas J. Hughes is a surgical technology instructor at San Joaquin Valley College in Fresno, California. He graduated from Boise State University in 2009 with a Bachelor of Applied Science degree with emphasis in Surgical Technology from Boise State University and is now an honors student in the Master of Arts in Education program at California State University, Fresno. Since 2006, he has worked in the operating room in several capacities, first as a sterile processing technician and instrumentation specialist and, most recently, as a first assistant in orthopedic surgery. Doug also serves the profession as the vice president of the Association of Surgical Assistants and is the administrator and webmaster of Surgical Assistant Resource.

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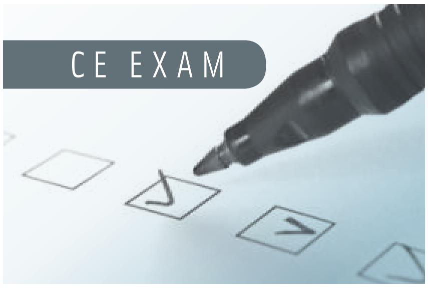

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Automated Anesthesia and Natural Orifice

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1. McSleepy is a ______________.
a. Car
b. Robotic system
c. Computer
d. None of the above

2. Closed-loop anesthesia systems utilize complex ______________ based on patient data.
a. Algorithms
b. Pharmacokinetics
c. Biological factors
d. Computer systems

3. McSleepy is commonly referred to as an ____________ robot.
a. Surgery
b. Anesthesiologist
c. Anesthesia
d. Excellent

4. McSleepy lends itself to revolutionizing patient care by ___________.
a. Improving patient care
b. Giving more accurate dosing
c. None of the above
d. Both a and b

5. Natural orifice transluminal endoscopic surgery shows potential to further alter the state of ___________ and treatment.
a. Surgeries
b. Disease diagnosis
c. Recovery
d. Internal complications

6. NOTES has greatly enhanced recovery of the surgical patient while simultaneously decreasing ______________.
a. Morbidity
b. Postoperative pain
c. Healing time
d. All of the above

7. The McSleepy anesthesia robot was combined with the DaVinci surgical robot to perform the world's first ______________.
a. Total-robotic operation
b. Heart surgery
c. Knee replacement
d. All of the above

8. Natural orifice transluminal endoscopic surgery is a ____________________.
a. Large-scale procedure
b. Minimally-invasive operation
c. Laparoscopic procedure
d. Both b and c

9. NOTES utilizes the body's natural ___________ to access internal abdominal organs and structures without leaving an external scar.
a. Fluids
b. Clock
c. Orifices
d. Organs

10. Five approaches to NOTES peritoneal access have been identified. They include ___________.
a. Transcolonic
b. Transgastric
c. Transvesical
d. All of the above

11. NOTES is a scarless procedure that is a combination of ____________ techniques.
a. Endoscopic
b. Laparoscopic
c. Both a and c
d. None of the above

Transluminal Endoscopic Surgery

12. One critical drawback to NOTES is the lack of adequate surgical instrumentation and equipment needed to facilitate ____________ procedures on humans.

a. Fully transluminal
b. Laparoscopic
c. Internal
d. External

13. As new NOTES technologies are developed they will lead us to ____________.

a. No-scar surgery
b. Minimal complications
c. Both A and B
d. None of the above

14. Advancements in NOTES procedures will help with ____________.

a. Time needed to administer anesthesia
b. Dissection
c. Decreases in tissue trauma
d. Elimination of muscle mass

15. ______________ may very well revolutionize the healthcare industry.

a. Automated, closed-loop anesthesia systems
b. NOTES
c. McSleepy
d. All of the above

16. McSleepy monitors the patient's level of ______________.

a. Pain
b. Consciousness
c. Muscle movement
d. All of the above

17. The natural orifice approach holds potential to __________ patient complications and ____________ postoperative recovery time.

a. Increase, reduce
b. Reduce, improve
c. Raise, lower
d. Reduce, increase

18. Experimenters such as Reginald Bickford used ___________ to monitor amounts of anesthetic administered to the patient.

a. EEG
b. BIS
c. Both A and B
d. None of the above

19. McSleepy was successfully tested during a ____________ procedure.

a. Anesthesia environment
b. Partial nephrectomy
c. Elbow replacement
d. Open heart surgery

20. Hemmerling described McSleepy as a ______________.

a. Advanced robot
b. Humanoid anesthesiologist
c. Human counterpart
d. Human competitor

AUTOMATED ANESTHESIA AND NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY 332 **AUGUST 2011** 2 CE credits

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2	☐	☐	☐	☐	12	☐	☐	☐	☐
3	☐	☐	☐	☐	13	☐	☐	☐	☐
4	☐	☐	☐	☐	14	☐	☐	☐	☐
5	☐	☐	☐	☐	15	☐	☐	☐	☐
6	☐	☐	☐	☐	16	☐	☐	☐	☐
7	☐	☐	☐	☐	17	☐	☐	☐	☐
8	☐	☐	☐	☐	18	☐	☐	☐	☐
9	☐	☐	☐	☐	19	☐	☐	☐	☐
10	☐	☐	☐	☐	20	☐	☐	☐	☐

Mark one box next to each number.
Only one correct or best answer can be selected for each question.