Balloon Dilatational Tracheostomy: Initial Experience with the Ciaglia Blue Dolphin Method

Tom W. Gromann, MD

Oliver Birkelbach, MD

Roland Hetzer, MD, PhD

BACKGROUND: Percutaneous dilational tracheostomy has become an established technique for ensuring safe and uncomplicated access to the respiratory systems of patients undergoing prolonged intubation. We studied a new balloon dilation percutaneous dilational tracheostomy technique which primarily uses radial force to widen the tracheostoma, the Ciaglia Blue Dolphin system.

METHODS: We report our initial clinical experience with this method in 20 patients from a cardiosurgical intensive care unit. We analyzed the results with regard to the practical feasibility of balloon dilation as well as possible complications.

RESULTS: Tracheostomy surgery time averaged 3.3 ± 1.9 min. The new technique caused neither bleeding requiring treatment nor injuries of the posterior tracheal wall. Routine bronchoscopic checks revealed one fracture of a single tracheal cartilage ring (5%). One patient developed subcutaneous emphysema during the balloon dilation, but this regressed spontaneously without treatment. No wound infections or prolonged wound healing of the tracheostoma were observed in any patient. There were no differences in terms of practical feasibility or bleeding complications when skin incisions of different lengths were analyzed.

CONCLUSIONS: The balloon dilational tracheostomy proved to be a feasible, easy, and successful technique. Its use of mainly radial force may reduce typical complications such as fractures of tracheal cartilage rings or injuries of the posterior tracheal wall. The new balloon-facilitated Ciaglia Blue Dolphin dilational tracheostomy technique uses mainly radial force to widen the tracheostoma. Radial outward dilation minimizes bleeding and injury to tracheal rings, and achieves good cosmetic results after decannulation. This technique proved to be a promising and efficient option for intensive care unit tracheostomies during our pilot trial.

(Anesth Analg 2009;108:1862–1866)

Percutaneous dilational tracheostomy (PDT) has become an established technique for ensuring safe and uncomplicated access to the respiratory systems of patients undergoing prolonged intubation. In the modern intensive care unit (ICU) it assists in respiratory weaning and improves pulmonary suctioning.[1] With this tracheostomy method, translaryngeal tracheal intubation complications can be avoided, weaning from the respirator is easier, and hygienic standards and patient comfort are increased.[1–3] The duration of treatment can also be greatly reduced and the mortality rate significantly decreased.[3,4]

The different PDT techniques have a low rate of intraoperative and postoperative complications at less expense, in terms of organization and personnel, compared with surgical tracheostomies.[1,5–7] The procedure can be easily and safely performed at the ICU bedside. At present, six tracheostomy techniques are in frequent use. The methodology, year of introduction, and principles of use are listed in Table 1. Currently, the advanced Ciaglia Blue Rhino technique is the most widely used procedure. It has had few complications, requires a short operative time and can be easily performed.[1]

Efforts to perfect the PDT produced the Ciaglia Blue Dolphin balloon dilation technique, which uses predominantly radial force to widen the tracheostoma.

We report the initial clinical experience with the Ciaglia Blue Dolphin System in 20 patients from a cardiosurgical ICU, and analyze the results in terms of practical feasibility of the balloon dilational tracheostomy and possible complications.

Besides performing the actual dilation technique, we recorded the skin incision, cosmetic results, coagulation time, and possible problems with healing of the wound. We also determined the optimal length of the skin incision for the dilational tracheostomy balloon technique.

METHODS

This prospective clinical study included every patient who received a PDT in a cardiosurgical ICU of the German Heart Institute Berlin in November and

From the Department of Cardiothoracic and Vascular Surgery, Deutsches Herzzentrum Berlin, Germany.

Accepted for publication December 12, 2008.

The authors have no conflict of interest to declare.

Address correspondence and reprint requests to Tom W. Gromann, MD, Deutsches Herzzentrum Berlin, Augustenburger Platz 1, D-13353 Berlin. Address e-mail to gromann@dhzb.de.

DOI: 10.1213/ane.0b013e3181a1a494

Table 1. Techniques Currently Used for Percutaneous Tracheostomy

Methodology	Year	Technique
Sequential dilators, Ciaglia	1985	Multistep dilation with sequential dilators, antegrade[8]
Dilating forceps, Griggs	1990	Dilation with specific forceps, antegrade[9]
Translaryngeal tracheostomy, Fantoni	1997	Retrograde passage; specific cannula acts as dilator and tracheostomy tube[10]
Single-step dilator, Ciaglia Blue Rhino	1999	Single-step dilation with a curved dilator and loading dilator, antegrade[11]
Dilating screw, Frova/Quintel	2002	Self-trapping screw, antegrade[12]
T-Dagger, Ambesh	2005	Single-step dilation with a curved, T-shaped dilator, elliptical in cross section, antegrade[13]
Balloon-facilitated dilational tracheostomy, Ciaglia Blue Dolphin	2005	Single-step dilation with balloon and loading dilator assembly, antegrade[14]

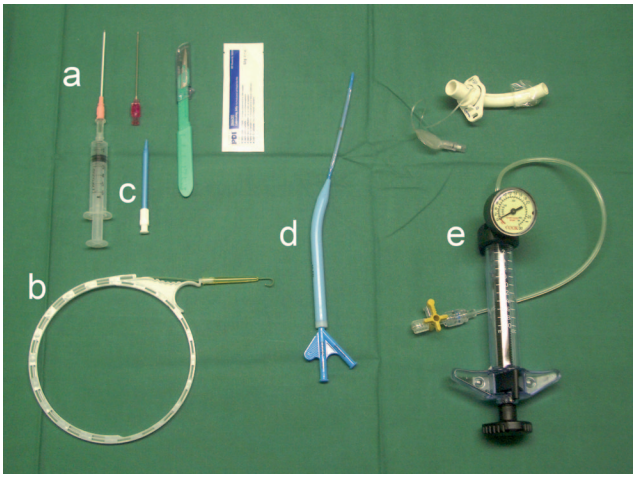

Figure 1. Ciaglia blue dolphin set balloon percutaneous tracheostomy introducer: introducer needle (a), wire guide (b), 14-French dilatator (c), balloon-tipped catheter loading dilatator assembly (d), Cook inflation device (e).

December 2007. This study was approved by our IRB, with waiver of need for patient consent.

The indication for the tracheostomy was the need for prolonged intubation or prolonged respiratory weaning due to muscular weakness, sepsis, acute pulmonary failure, pneumonia, low-output syndrome, or neurological dysfunction. Contraindications for a PDT were infections in the area of the operation, palpable unidentifiable structures of the trachea (landmark structures), and difficult conventional intubation. Consent of the patients or their next of kin was obtained.

Patients were monitored on a respirator (F_{IO_2} 1.0), and received sedative and analgesic doses of sufentanil/propofol or ketamine/midazolam and a neuromuscular blocking drug (pancuromium bromide). The operative surveillance followed our institution's clinical algorithms and included continuous electrocardiogram, invasive arterial blood pressure measurement, continuous pulse oximetry, and monitoring of airway pressures and exhaled tidal volumes.

The tracheostomies were performed at the ICU bedside using the Ciaglia Blue Dolphin Set (Ciaglia Blue Dolphin Balloon Percutaneous Tracheostomy Introducer, Cook Critical Care, Bloomington, IN). Individual components can be seen in Figure 1. For this evaluation phase we used tracheal tubes with an inner diameter of 8.0 mm (Mallinckrodt, Tyco Healthcare, Hazelwood, MO). In this pilot study two experienced anesthesiologists (authors) performed the tracheotomies and were responsible for the concurrent bronchoscopy.

Operative Method:

Adequate administration of oxygen and optimal placement of the patient, with full extension of the head and neck, were followed by surgical disinfection and sterile covering of the operative area. Using continuous bronchoscopic surveillance, the tracheal tube was withdrawn to the point where the tube cuff lies just below the vocal chords to be able to safely puncture the tracheal lumen.

After determination of the puncture site by manual examination of the cricoid cartilage and, if possible, diaphanoscopy, a 1 to 2 cm long horizontal surgical incision of the skin was made. The ensuing puncture of the trachea was monitored by bronchoscopy. The tracheal ring was typically punctured at the level between the second and third tracheal cartilage. Using the Seldinger technique, the wire guide was placed, and the puncture canal was enlarged with a short 14-French introducing dilator.

The procedures performed up to this point correspond to the established techniques for Ciaglia (Blue Rhino). To perform the new balloon dilational tracheostomy, the inflation device had to be filled with a minimum of 20 mL of normal saline. The prepared inflation device was then attached to the balloon port on the balloon catheter assembly. After removal of the 14-French dilator, the lubricated balloon-tipped catheter loading assembly with prepared tracheostomy tube was introduced as a unit over the wire guide remaining *in situ* (Fig. 2). Under bronchoscopic surveillance, the deflated balloon catheter was advanced into the trachea until only 1 to 1.5 cm of the balloon remained above skin level. The balloon was then filled with normal saline using the inflation pump until a maximum pressure of 11 atm was reached (Fig. 3). The maximum inflation pressure was held for 15 s. The puncture canal was enlarged by the balloon through the creation of outward radial pressure.

Subsequently, the balloon was completely deflated. The deflated balloon catheter/loading dilator/tracheostomy

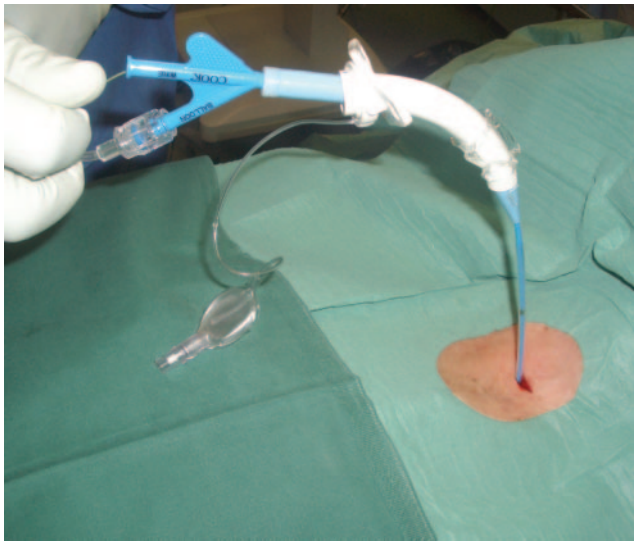

Figure 2. Advancement of the balloon catheter/loading dilatator unit with prepared tracheal cannula over the *in situ* wire guide.

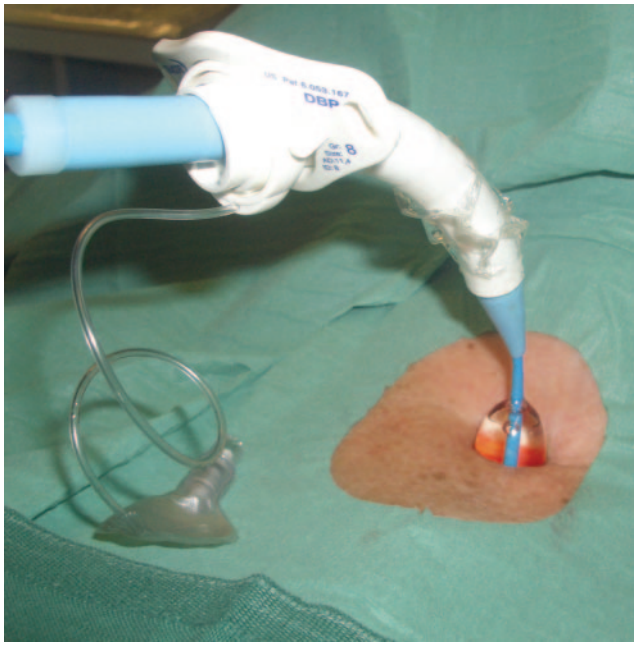

Figure 3. Balloon inflation with normal saline to a maximum pressure of 11 atm using an inflation pump; the balloon protrudes 1 to 1.5 cm above the skin line.

tube/wire guide assembly was then simultaneously advanced as a unit into the trachea. When the tracheostomy tube was in place, the rest of the assembly was removed. The skin of the tracheostoma immediately compressed itself to the tracheal cannula.

The tracheal tube balloon cuff was then inflated, and the correct placement of the cannula was verified by bronchoscopy. The respirator was then connected to the tracheal cannula and the orotracheal tube was removed.

RESULTS

During the study period, 548 patients were treated in the cardiosurgical ICUs at the German Heart Institute Berlin. The number of tracheotomized patients was 20 (eight women), corresponding to 3.6% of the patients treated. No patient was excluded from the study because of contraindications. Table 2 shows the surgical procedures performed on the patient collective.

Table 2. Operative Procedures: Distribution of the Patient Collective

Operative procedures	Patients (total)	Patients with high-dose heparin[a]
Coronary bypass surgery	3	2
Heart valve surgery	4	2
Coronary and heart valve surgery	3	1
Aortic surgery	2	—
Lung transplantation	2	—
Ventricular Assist Device surgery	3	3
Others[b]	3	1

[a] Activated partial thromboplastin time adjusted to twice the baseline, minimum 60 s.

[b] 1 myectomy, 1 cholecystectomy after ventricular assist device, 1 pericardial hematoma evisceration.

The average age was 64.5 yr; age range was 27 to 86 yr. The body mass index (BMI in kg/m^2) was between 16.8 and 35.4.

The 90-day mortality of the group of tracheostomized patients was 25% (five patients). All of these patients died of multiorgan failure. No patient died as a result of the PDT.

The length of time between translaryngeal tracheal intubation and PDT was, on average, 7 days, and ranged from 1 day on a respirator, where an early elective tracheostomy after a lung transplantation was performed, to 22 days.

The prothrombin time directly before PDT was 71% ± 11.6% compared with normal pool plasma (100% of norm), the activated partial thromboplastin time was 46 ± 8.5 s, and the average number of thrombocytes in plasma was 149 ± 119 μ/L. Heparinization of the patients was not discontinued at any time. Average tracheostomy surgery time (from tracheal puncture to tracheostomy placement) was 3.3 min (range, 1.5–9 min).

There were three different horizontal incision lengths: 10 mm in six patients, 15 mm in seven patients, and 20 mm in seven patients. With regard to BMI and age, the three groups were comparable. In one patient, because of a scar from a previous thyroidectomy in the operative area, a 20 mm incision with three dilation procedures was needed before safe airway passage was attained.

The balloon pressure of the Cook Blue Dolphin Systems was 11 atm and the time needed for balloon dilation was 15 s in all cases. The new technique did not cause bleeding requiring treatment, or injuries of the posterior tracheal wall. Routine bronchoscopy control revealed one fracture of a single tracheal cartilage ring. One patient developed subcutaneous emphysema during the balloon dilation, but this did not require any additional treatment, and the balloon

dilational tracheostomy was completed using the same set.

The average postoperative duration of cannulation was 22 days, with a range between 6 and 69 days. No infections of the tracheostomy were reported. The follow-up time was 90 days. Half of the patients were successfully weaned from their respirators and were decannulated. Five patients were transferred to other hospitals with their tracheostomies.

DISCUSSION

The pioneering work by Ciaglia et al.[8] published in 1985 has led to the widespread use of the dilation technique for tracheostomies over the past 20 yr. Ensuring a safe airway passage with an elective PDT is now an established part of the strategy used for careful invasive mechanical respiratory therapy and for weaning of long-term patients on respirators.

The validity of the PDT after cardiosurgical intervention has been proven.[15,16] Comprehensive data on the techniques of dilative tracheostomy have been collected since 1995 by the German Heart Institute Berlin.[16] Over the past 13 yr, there have been more than 40,000 operations with 1350 postoperative dilative tracheostomies. Our results are comparable with those of published reports in which the percentage of intensive care patients with a tracheostomy was approximately 4%.[15] This large body of experience and increasing knowledge of the positive effects of the PDT justify a noticeable trend, also seen in our clinic, toward an early elective tracheostomy.[3]

These operations have proven to be safe and practical in daily clinical use. However, despite presumed minimal tissue trauma, PDT still has serious and intermediate early and late complications, with a frequency of approximately 6%.[17–19] Thus, efforts to perfect the current methods of tracheostomy have considerable relevance for the care of our intensive care patients.

An optimal method should enable the tracheostomy to be achieved in a very short time period, with minimal personnel and technical requirements and with very low risk. The method first used by Zgoda and Berger is more than just a simple variation of the established method, and uses outward radial dilation with a balloon in the puncture canal.[14] Compression of the anterior tracheal wall is, for the most part, avoided through use of a laterally adjusted pressure component.

Our study proved that this new method is technically easy to perform and can be learned in a short time. All tracheostomies using the Blue Dolphin Set ended successfully. We were able to correctly place the tracheal cannula in each patient without great effort. The bronchoscope confirmed that this dilative process with a balloon is possible without damage to the tracheal lumen. Fractures of the tracheal rings are potential complications of PDTs. The frequency, taken from various investigations, is 25%.[11,20] We observed a fracture of the tracheal ring in one patient during our series of 20 operations. The careful outward radial dilation is certainly one factor in avoiding this kind of complication. However, endoscopic monitoring and precise puncture between the tracheal rings seemed more significant.

During dilative tracheostomies, injuries with bleeding because of damage to large or atypical blood vessels have been described with a frequency of approximately 7%.[16,18,21] Our experience shows that patients with moderate disruptive hemostasis and anticoagulation after receiving a ventricular assist device or a mechanical heart valve can be safely tracheotomized. The anticoagulation was not discontinued or reduced in dose in our patients. Table 2 shows the number of patients treated with high dose heparin in our collective. The well directed radial force of the balloon dilational tracheostomy for 15 s secures surprisingly efficient hemostasis. Despite the required skin incision, the technique did not cause bleeding.

There seems to be an increased appearance of complications in adipose patients receiving a dilative tracheostomy.[19] However, we used the balloon-supported method without complications in four patients with a BMI more than 30 kg/m^2.

Despite our limited experience with balloon dilation and the necessary learning curve, the operation time (from the actual tracheal puncture to ventilation via the tracheal cannula) was approximately 3 min in our study. During these procedures there was no deterioration of the blood oxygen saturation levels, which were continuously measured using pulse oximetry. The present operation times correspond to published data for different tracheostomy methods.[6,11] Experienced surgeons can complete a dilative tracheostomy in <3 min. The advantages of a shorter time with regard to perioperative blood gas problems are, in our view, not clinically relevant. Future efforts should not focus on further reducing the tracheostomy time but rather on developing a procedure with minimal tissue trauma.

The new dilational method requires a skin incision. The necessary incision influences the coagulation time, and the cosmetic results, but there is insufficient knowledge with regard to the optimal skin incision length. There were no differences in terms of practical feasibility or bleeding complications among the groups with different lengths of skin incisions. The 10 mm incision group showed a distinctive circular constriction of the balloon ("sandglass phenomenon") (Fig. 4). Based on our experience, we currently recommend a skin incision of at least 15 mm.

Our pilot study is limited by the small number of patients, and further studies in larger patient populations are required. The data were not randomized and no comparison was made with tracheostomy using other methods.

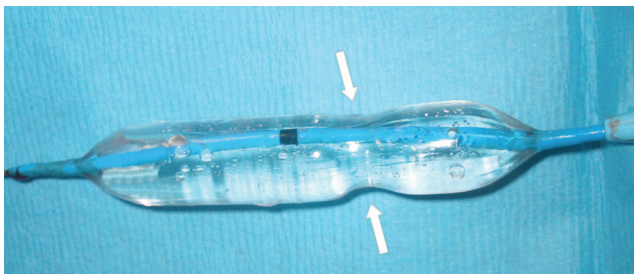

Figure 4. Distinctive circular constriction of the balloon.

The following questions need to be answered: Can typical complications be further reduced? How can we optimize the cosmetic outcome?

On the basis of our results from the ICU of a large cardiosurgical hospital, we conclude that the Ciaglia Blue Dolphin technique is a feasible and viable option in ICU patients despite anticoagulation. Radial outward dilation minimizes bleeding and injury to tracheal rings, and achieves good cosmetic results after decannulation.

ACKNOWLEDGMENTS

The authors are grateful to Anne Gale and Jay Wiley for editorial assistance.

REFERENCES

1. De Leyn P, Bedert L, Delcroix M, Depuydt P, Lauwers G, Sokolov Y, Van Meerhaeghe A, Van Schil P; Belgian Association of Pneumology and Belgian Association of Cardiothoracic Surgery. Tracheotomy: clinical review and guidelines. Eur J Cardiothorac Surg 2007;32:412–21
2. Griffiths J, Barber VS, Morgan L, Young JD. Systematic review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation. BMJ 2005;330:1243
3. Rumbak MJ, Newton M, Truncale T, Schwartz SW, Adams JW, Hazard PB. A prospective, randomized, study comparing early percutaneous dilational tracheotomy to prolonged translaryngeal intubation (delayed tracheotomy) in critically ill medical patients. Crit Care Med 2004;32:1689–94
4. Rodriguez JL, Steinberg SM, Luchetti FA, Gibbons KJ, Taheri PA, Flint LM. Early tracheostomy for primary airway management in the surgical critical care setting. Surgery 1990;108:655–9
5. Bacchetta MD, Girardi LN, Southard EJ, Mack CA, Ko W, Tortolani AJ, Krieger KH, Isom OW, Lee LY. Comparison of open versus bedside percutaneous dilatational tracheostomy in the cardiothoracic surgical patient: outcomes and financial analysis. Ann Thorac Surg 2005;79:1879–85
6. Higgins KM, Punthakee X. Meta-analysis comparison of open versus percutaneous tracheostomy. Laryngoscope 2007;117:447–54
7. Silvester W, Goldsmith D, Uchino S, Bellomo R, Knight S, Seevanayagam S, Brazzale D, McMahon M, Buckmaster J, Hart GK, Opdam H, Pierce RJ, Gutteridge GA. Percutaneous versus surgical tracheostomy: a randomized controlled study with long-term follow-up. Crit Care Med 2006;34:2145–52
8. Ciaglia P, Firsching R, Syniec C. Elective percutaneous dilatational tracheostomy. A new simple bedside procedure; preliminary report. Chest 1985;87:715–19
9. Griggs WM, Worthley LI, Gilligan JE, Thomas PD, Myburg JA. A simple percutaneous tracheostomy technique. Surg Gynecol Obstet 1990;170:543–5
10. Fantoni A, Ripamonti D. A non-derivative, non-surgical tracheostomy: the translaryngeal method. Intensive Care Med 1997;23:386–92
11. Byhahn C, Lischke V, Halbig S, Scheifler G, Westphal K. [Ciaglia blue rhino: a modified technique for percutaneous dilatation tracheostomy. Technique and early clinical results]. Anaesthesist 2000;49:202–6
12. Frova G, Quintel M. A new simple method for percutaneous tracheostomy: controlled rotating dilation. A preliminary report. Intensive Care Med 2002;28:299–303
13. Ambesh SP, Tripathi M, Pandey CK, Pant KC, Singh PK. Clinical evaluation of the "T-Dagger": a new bedside percutaneous dilational tracheostomy device. Anaesthesia 2005;60:708–11
14. Zgoda MA, Berger R. Balloon-facilitated percutaneous dilational tracheostomy tube placement: preliminary report of a novel technique. Chest 2005;128:3688–90
15. Rahmanian PB, Adams DH, Castillo JG, Chikwe J, Filsoufi F. Tracheostomy is not a risk factor for deep sternal wound infection after cardiac surgery. Ann Thorac Surg 2007;84:1984–91
16. Wagner F, Nasseri R, Laucke U, Hetzer R. Percutaneous dilatational tracheostomy: results and long-term outcome of critically ill patients following cardiac surgery. Thorac Cardiovasc Surg 1998;46:352–6
17. Cosgrove JE, Sweenie A, Raftery G, Carey SM, Kilner AJ, Nesbitt ID, Cressey DM, Hirschauer N, Laws PG, Ryan DW. Locally developed guidelines reduce immediate complications from percutaneous dilatational tracheostomy using the Ciaglia Blue Rhino technique: a report on 200 procedures. Anaesth Intensive Care 2006;34:782–6
18. Kearney PA, Griffen MM, Ochoa JB, Boulanger BR, Tseui BJ, Mentzer RM Jr. A single-center 8-year experience with percutaneous dilational tracheostomy. Ann Surg 2000;231:701–9
19. Kost KM. Endoscopic percutaneous dilatational tracheotomy: a prospective evaluation of 500 consecutive cases. Laryngoscope 2005;115:1–30
20. Beiderlinden M, Karl Walz M, Sander A, Groeben H, Peters J. Complications of bronchoscopically guided percutaneous dilational tracheostomy: beyond the learning curve. Intensive Care Med 2002;28:59–62
21. Pandit RA, Jacques TC. Audit of over 500 percutaneous dilational tracheostomies. Crit Care Resusc 2006;8:146–50