の術前情報，術中情報をもとにそれぞれの項目のリスク因子から死亡率を予測する）と Risk Calculator（手術を受ける患者さんの術後 30 日死亡予測発生率，手術関連死亡予測発生率を計算する）機能，そして，施設診療科の患者背景とパフォーマンスの全国比較（患者さんの術前リスクに関する項目の集計結果，および登録データに基づいて推定された自施設診療科の予測死亡率から，全国と比較し自施設診療科がどのような傾向，特徴をもっているか把握する）を NCD Feedback 機能として，食道切除再建術，胃全摘術，結腸右半切除術，低位前方切除術，膵頭十二指腸切除術，肝切除術についてリリースした．さらに，2011，2012 両年のデータを用いて，医療水準評価 8 術式に関する合併症の論文化を各々の術式について進めているところである．

今後引き続き，より詳細なデータの公表により本邦の消化器外科医療の現況を周知していく予定である．

3. 対象と方法

今回対象としたのは，NCD に登録された症例データのうち，一般社団法人日本消化器外科学会が消化器外科専門医認定審査のための消化器外科専門医修練カリキュラムに定めた手術（新手術難易度区分）に関するデータである．115 の消化器外科専門医術式については既に Annual Report 2011–2012 で報告したデータも 2011 年と 2012 年に分け，2011 年，2012 年，2013 年のデータを対象とした．さらに，これらのうち医療水準を測るうえで重要となる術式については，主たる 8 術式として 115 術式とは別に検討した．

今回は，115 の消化器外科専門医術式に関する手術症例数と死亡率，そして主たる 8 術式に関する手術症例数と死亡率における，2011 年，2012 年，2013 年の経年的変化を明らかにした．また，主たる 8 術式に関する患者性別および年齢区分，施設区分および専門医関与の割合を比較検討した．

4. データ解釈における注意点

今回の報告においては，データの解釈上，以下の点での留意が必要である．

（1）NCD では 1 症例に対して最大 8 術式までの登録が可能となっているため，「5. 消化器外科専門医 115 術式に関する調査」における手術件数の合計が実際の手術症例数の合計とはならない．

（2）患者年齢，性別，術後 30 日状態の登録に不備のある症例は除外した．

（3）同時に複数の術式が施行された症例も全て術式ごとに集計した．

（4）術後 30 日死亡は，入院中，退院後にかかわらず術後 30 日以内の全ての死亡を含み，手術関連死亡は，術後 30 日死亡と術後 90 日以内の在院死亡を合わせたものである．

5. 消化器外科専門医 115 術式に関する結果

2011 年 1 月 1 日から 2013 年 12 月 31 日までの 3 年間に NCD に登録された消化器外科専門医 115 術式の総数は 1,494,934 例で，臓器別にみると食道 24,707 例（1.7%），胃・十二指腸 218,509 例（14.6%），小腸・結腸 534,630 例（35.8%），直腸・肛門 140,745（9.4%），肝 75,458 例（5.0%），胆 354,858 例（23.7%），膵 45,407 例（3.0%），脾 12,260 例（0.8%），その他 88,360 例（5.9%）であった（**表 1**）．男女比は全体で約 6:4 であり，年齢区分でみると全体の 16.0%が 80 歳以上であるが，特に胃・十二指腸，小腸・結腸，直腸・肛門では 80 歳以上の比率が高かった（**表 1**，**図 1**）．

手術の行われた施設区分では，全体では約 7 割が認定施設で行われ，特に食道（87.0%），肝（82.9%），膵（82.3%），脾（80.0%）では認定施設で行われた手術の比率が高かった．麻酔科医関与の比率は 90.9%であり，66.4%の手術が専門医の関与のもとに行われていた（**表 2**）．食道（63.3%），肝（56.6%），膵（59.4%）は専門医が術者となる率が高かった（**表 2**）．

総手術件数は 432,740（2011 年），517,084（2012 年），545,110（2013 年）と経年的に増加し，術後 30 日

表1　消化器外科専門医115術式の臓器別手術件数と性別，年齢区分（2011年，2012年，2013年総計）

臓器	手術件数	性別の比率（%）		年齢区分の比率（%）					
		男	女	60歳未満	60歳以上65歳未満	65歳以上70歳未満	70歳以上75歳未満	75歳以上80歳未満	80歳以上
食道	24,707	81.8	18.2	21.7	18.9	20.7	19.6	12.7	6.3
胃・十二指腸	218,509	68.1	31.9	19.2	14.0	14.7	17.1	16.6	18.4
小腸・結腸	534,630	56.7	43.3	36.4	10.5	10.9	12.4	12.4	17.4
直腸・肛門	140,745	58.4	41.6	21.7	14.9	14.8	15.7	14.4	18.6
肝	75,458	66.4	33.6	21.8	15.5	16.9	18.4	17.3	10.0
胆	354,858	55.1	44.9	33.2	13.5	12.6	14.0	13.1	13.6
膵	45,407	59.9	40.1	19.6	14.8	17.3	20.0	17.9	10.5
脾	12,260	61.5	38.5	32.8	15.6	15.2	15.5	12.7	8.1
その他	88,360	54.3	45.7	30.2	11.4	12.0	13.8	14.2	18.3
計	1,494,934	59.1	40.9	29.9	12.8	13.0	14.5	13.9	16.0

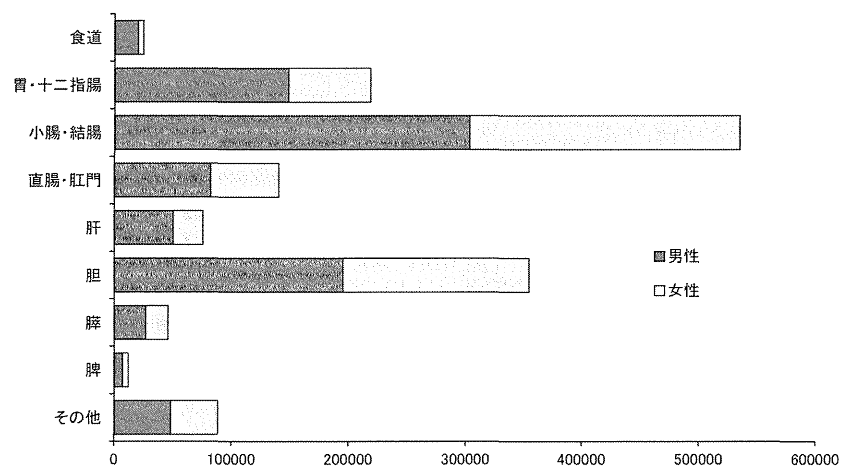

図1　消化器外科専門医115術式の臓器別手術件数と性別（2011年，2012年，2013年総計）

表2　消化器外科専門医115術式における臓器別にみた施設区分と麻酔科医，専門医の関与（2011年，2012年，2013年総計）

臓器	手術件数	施設区分の比率（%）			麻酔科医関与の比率（%）	専門医関与の比率（%）	術者（%）	
		認定施設	関連施設	その他			専門医	非専門医
食道	24,707	87.0	6.3	6.7	97.3	87.5	63.3	36.7
胃・十二指腸	218,509	73.0	17.4	9.6	93.2	71.1	36.2	63.8
小腸・結腸	534,630	69.7	20.2	10.1	88.9	60.8	25.8	74.2
直腸・肛門	140,745	69.6	19.7	10.7	86.4	69.4	38.0	62.0
肝	75,458	82.9	9.9	7.2	95.7	86.2	56.6	43.4
胆	354,858	66.8	22.1	11.1	92.0	63.5	26.7	73.3
膵	45,407	82.3	10.2	7.5	96.0	86.5	59.4	40.6
脾	12,260	80.0	11.7	8.3	95.1	75.5	44.1	55.9
その他	88,360	73.8	17.4	8.8	91.0	61.9	27.9	72.1
計	1,494,934	71.1	18.9	9.9	90.9	66.4	32.1	67.9

表3　消化器外科専門医115術式における臓器別の手術件数と死亡率（2011年，2012年，2013年総計）

臓器	手術件数	術後30日死亡数/率（%）	手術関連死亡数/率（%）
食道	24,707	325/1.3	921/3.7
胃・十二指腸	218,509	3,136/1.4	6,833/3.1
小腸・結腸	534,630	10,230/1.9	18,776/3.5
直腸・肛門	140,745	1,374/1	2,336/1.7
肝	75,458	901/1.2	1,779/2.4
胆	354,858	1,560/0.4	3,158/0.9
膵	45,407	599/1.3	1,305/2.9
脾	12,260	246/2	414/3.4
その他	88,360	3,963/4.5	6,526/7.4
計	1,494,934	22,334/1.5	42,048/2.8

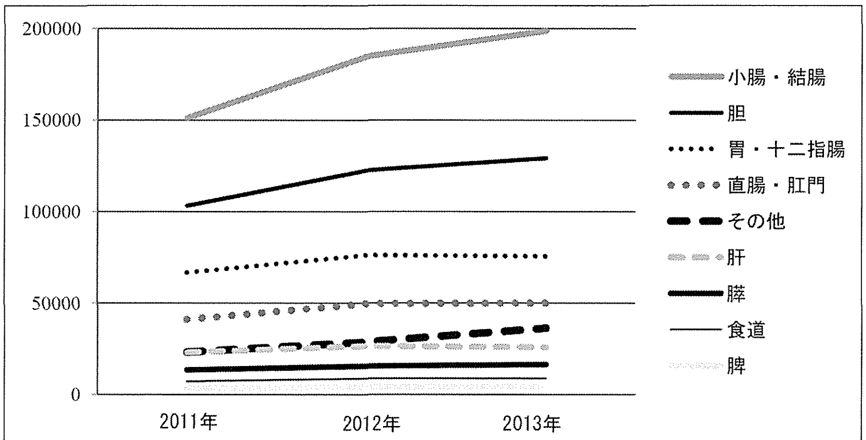

図2　消化器外科専門医115術式の臓器別手術件数の年次推移

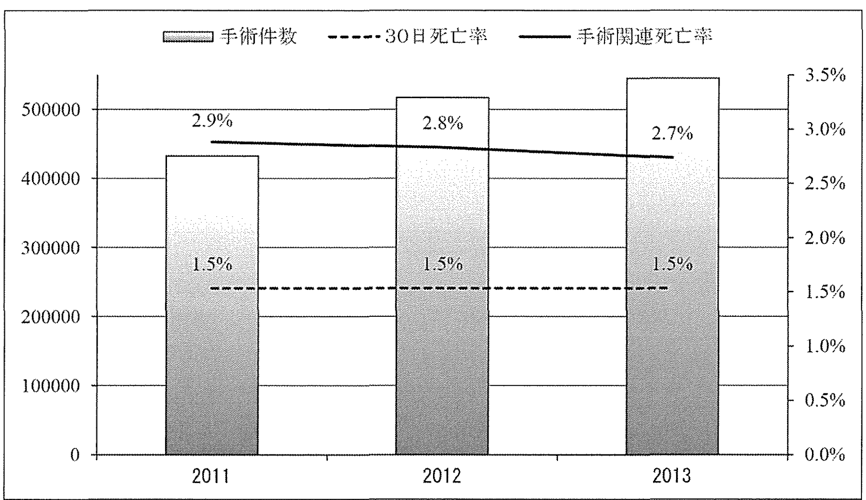

図3　消化器外科専門医115術式の手術件数と死亡率の年次推移

死亡率と手術関連死亡率は，それぞれ1.5%，2.9%（2011年），1.5%，2.8%（2012年），1.5%，2.7%（2013年）であった（表3，図2，図3）．消化器外科専門医115術式の臓器別の死亡率を図4に示す．

消化器外科専門医115術式の術式別手術件数を，登録年別に表4〜12に臓器別に示した．

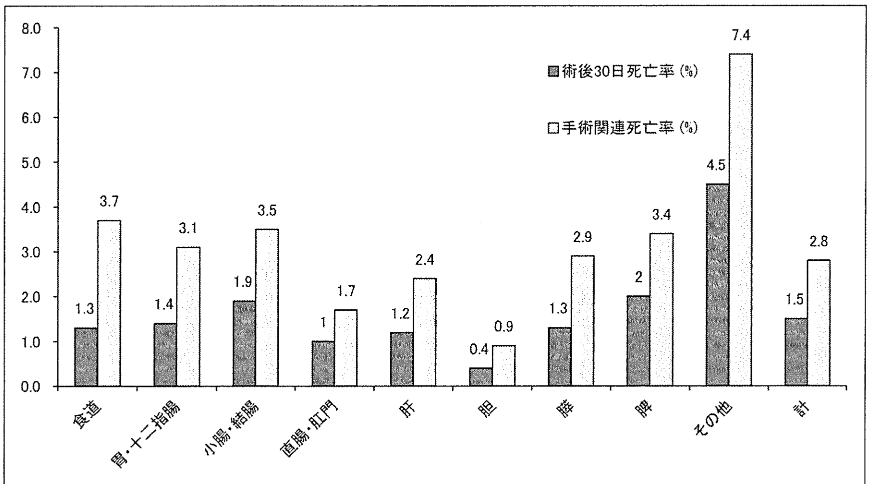

図 4　消化器外科専門医 115 術式の臓器別の死亡率（2011 年，2012 年，2013 年総計）

表 4　消化器外科専門医 115 術式の術式別手術件数の年次推移（食道）

臓器	難度	術式名	手術件数		
			2011 年	2012 年	2013 年
食道	低	頸部食道周囲膿瘍ドレナージ	23	27	34
	中	食道縫合術（穿孔，損傷）	156	204	198
	中	胸部食道周囲膿瘍ドレナージ	22	23	18
	中	食道異物摘出術	19	21	26
	中	食道憩室切除術	27	32	35
	中	食道良性腫瘍摘出術	61	69	66
	中	食道切除術（切除のみ）	388	506	580
	中	食道再建術再建のみ（胃管再建）	699	844	888
	中	食道瘻造設	97	106	128
	中	食道噴門形成術	321	418	392
	中	アカラシア手術	77	109	84
	高	食道切除再建術	4,916	5,946	5,694
	高	食道再建術再建のみ（結腸再建）	65	56	63
	高	食道バイパス術	93	110	137
	高	食道気管支瘻手術	6	5	9
	高	食道二次的再建術	276	343	290

表 5　消化器外科専門医 115 術式の術式別手術件数の年次推移（胃・十二指腸）

臓器	難度	術式名	手術件数		
			2011 年	2012 年	2013 年
胃・十二指腸	低	胃切開・縫合術	52	69	74
	低	憩室，ポリープ切除術（内視鏡的切除は除く）	156	186	231
	低	幹迷走神経切離術	3	6	6
	低	胃腸吻合術（十二指腸空腸吻合術を含む）	4,651	5,330	5,571
	低	胃瘻造設術（PEG を除く）	1,717	1,698	1,633
	低	幽門形成術	116	129	115
	低	胃捻転症（軸捻症）手術・吊り上げ固定術手術	40	38	39
	低	胃縫合術（胃破裂に対する胃縫合，胃・十二指腸穿孔に対する縫合閉鎖術，大網充填術，大網被覆術を含む）	4,707	5,738	5,669
	低	胃局所切除術（楔状切除を含む）	2,466	3,108	3,233
	中	胃切除術（幽門側胃切除術，幽門保存胃切除術，文節（横断）胃切除術を含む）	34,160	38,750	39,957
	中	選択的迷走神経切離術	8	8	10
	高	胃全摘術（噴門側胃切除術を含む）	18,652	21,122	19,035
	高	左上腹部内蔵全摘術	12	4	10

表6　消化器外科専門医115術式の術式別手術件数の年次推移（小腸・結腸）

臓器	難度	術式名	手術件数		
			2011年	2012年	2013年
小腸・結腸	低	腸切開・縫合術	2,982	3,505	4,025
	低	腸重積整復術（観血的）	172	250	234
	低	小腸部分切除術（良性）	5,792	7,602	8,564
	低	回盲部切除術（良性）	3,238	4,104	4,313
	低	結腸部分切除術・S状結腸切除術（良性）	4,946	6,239	6,626
	低	虫垂切除術	43,437	51,316	54,421
	低	腸瘻造設・閉鎖術（腸管切除なし）	15,192	19,371	21,600
	中	小腸切除術（悪性）	2,448	2,703	3,016
	中	回盲部切除術（悪性）	5,492	9,274	10,327
	中	結腸部分切除術・S状結腸切除術（悪性）	25,034	29,863	31,495
	中	結腸右半切除術	17,890	21,034	21,814
	中	結腸左半切除術	5,241	5,347	5,644
	中	結腸全摘除術	2,846	3,131	1,892
	中	腸閉塞症手術（腸管切除を伴う）	5,117	6,496	7,412
	中	腸瘻造設・閉鎖術（腸管切除あり）	11,008	14,162	16,853
	高	大腸全摘回腸肛門（管）吻合術	308	413	441

表7　消化器外科専門医115術式の術式別手術件数の年次推移（直腸・肛門）

臓器	難度	術式名	手術件数		
			2011年	2012年	2013年
直腸・肛門	低	経肛門的直腸腫瘍摘出術	2,483	3,300	1,657
	低	直腸脱手術（経肛門的）	1,802	2,461	2,488
	中	直腸切断術（良性）	300	386	2,196
	中	高位前方切除術	7,053	8,920	8,985
	中	Hartmann手術	3,562	4,614	4,865
	中	直腸脱手術（腹会陰式）	659	996	1,119
	中	直腸・肛門悪性腫瘍切除術（経肛門的）	1,517	1,037	898
	中	肛門括約筋形成術（組織置換による）	969	1,378	1,721
	高	直腸切断術（悪性）	5,308	5,828	4,474
	高	低位前方切除術	16,984	20,321	21,096
	高	骨盤内臓器全摘術	359	389	412
	高	直腸・肛門悪性腫瘍切除術（後方アプローチ）	65	74	69

表8　消化器外科専門医115術式の術式別手術件数の年次推移（肝）

臓器	難度	術式名	手術件数		
			2011年	2012年	2013年
肝	低	肝縫合術	172	202	161
	低	肝膿瘍ドレナージ術（経皮的手技を除く）	42	47	54
	低	肝嚢胞切開．縫縮．内瘻術	425	535	606
	低	肝部分切除術	9,431	10,919	10,708
	低	肝バイオプシー（経皮的手技を除く）	122	264	176
	低	肝凝固壊死療法術（経皮的手技を除く）	1,958	2,122	1,083
	中	肝外側区域切除	1,390	1,632	1,773
	中	食道・胃静脈瘤手術	94	109	67
	高	肝切除術（外側区域を除く区域以上）	7,434	8,239	7,937
	高	系統的亜区域切除術	996	1,353	2,374
	高	肝移植術	692	775	757
	高	肝膵同時切除術	99	91	118

表9　消化器外科専門医115術式の術式別手術件数の年次推移（胆）

臓器	難度	術式名	手術件数 2011年	2012年	2013年
胆	低	胆管切開術	142	163	174
	低	胆嚢切開切石術	1,094	1,093	750
	低	胆嚢摘出術	93,665	112,048	119,455
	低	胆嚢外瘻術	104	119	127
	低	胆嚢消化管吻合術	70	73	61
	中	胆管切開切石術	3,682	4,117	3,880
	中	胆道再建術	150	162	265
	中	胆道バイパス手術	1,594	1,751	1,765
	中	胆管形成術	201	180	192
	中	十二指腸乳頭形成術	66	68	50
	中	総胆管拡張症手術	217	240	254
	中	胆汁瘻閉鎖術	43	42	42
	高	胆嚢悪性腫瘍手術（単純胆嚢摘出術を除く）	869	1,013	929
	高	胆管悪性腫瘍手術	1,268	1,426	1,202
	高	胆道閉鎖症手術	18	18	16

表10　消化器外科専門医115術式の術式別手術件数の年次推移（膵）

臓器	難度	術式名	手術件数 2011年	2012年	2013年
膵	低	膵嚢胞外瘻術	29	27	13
	低	膵管外瘻術	17	20	26
	中	膵縫合術	22	17	21
	中	膵部分切除術	126	148	202
	中	膵体尾部切除術（良性）	1,018	1,398	1,372
	中	膵嚢胞消化管吻合術	81	71	59
	中	膵（管）消化管吻合術	223	295	309
	中	急性膵炎手術	94	117	104
	中	膵石症手術	17	17	14
	中	膵頭神経叢切除術	1	1	2
	高	膵頭十二指腸切除術	8,305	9,329	10,068
	高	膵体尾部切除術（悪性）	2,861	3,344	3,483
	高	膵全摘術	348	408	423
	高	十二指腸温存膵頭切除術	201	193	111
	高	膵区域切除術	131	163	138
	高	膵体尾側切除術	3	2	35

表11　消化器外科専門医115術式の術式別手術件数の年次推移（脾）

臓器	難度	術式名	手術件数 2011年	2012年	2013年
脾	低	脾縫合術	22	35	26
	中	脾摘術	3,564	4,063	4,457
	中	脾部分切除術	23	44	26

表 12　消化器外科専門医 115 術式の術式別手術件数（その他）

臓器	難度	術式名	手術件数		
			2011 年	2012 年	2013 年
その他	低	限局性腹腔膿瘍手術	2,526	2,944	3,231
	低	試験開腹術	5,036	6,852	7,532
	中	急性汎発性腹膜炎手術	7,753	9,177	10,447
	中	腹壁ヘルニア手術	5,053	6,095	11,387
	中	横隔膜縫合術	183	218	246
	中	食道裂孔ヘルニア手術	511	602	725
	中	後腹膜腫瘍手術	622	837	806
	中	腹壁・腸間膜・大網腫瘍切除	979	1,398	1,402
	中	消化管穿孔部閉鎖術	504	576	522
	高	横隔膜裂孔ヘルニア手術	51	80	65

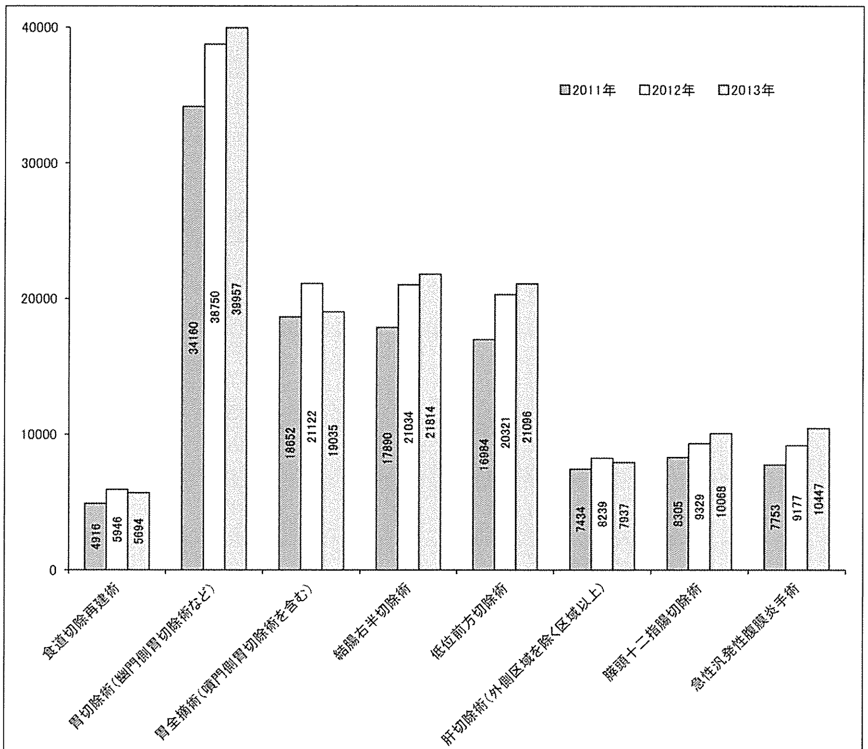

図 5　主たる 8 術式の臓器別手術件数の年次推移

6. 主たる 8 術式に関する結果

2011 年 1 月 1 日から 2013 年 12 月 31 日の 3 年間に行われた主たる 8 術式の手術件数は年次別（2011 年，2012 年，2013 年）に，食道切除再建術 4,916 例，5,946 例，5,694 例，胃切除術（幽門側）34,160 例，38,750 例，39,957 例，胃全摘術 18,652 例，21,122 例，19,035 例，結腸右半切除術 17,890 例，21,034 例，21,814 例，低位前方切除術 16,984 例，20,321 例，21,096 例，肝切除術（外側区域以外の区域）7,434 例，8,239 例，7,937 例，膵頭十二指腸切除術 8,305 例，9,329 例，10,068 例，急性汎発性腹膜炎手術 7,753 例，9,177 例，10,447 例であった（図 5）．

以後，2013 年の症例数で検討すると，男女比は全ての術式で男性が多く，特に食道切除再建術，胃切除術（幽門側），肝切除術で男性が優位であった．また，胃切除術（幽門側），結腸右半切除術，急性汎発性

表13　主たる8術式の手術件数と性別，年齢区分（2013年）

術式	手術件数	性別の比率（%）		年齢区分の比率（%）					
		男	女	60歳未満	60歳以上65歳未満	65歳以上70歳未満	70歳以上75歳未満	75歳以上80歳未満	80歳以上
食道切除再建術	5,694	83.6	16.4	18.3	18.3	22.6	21.3	13.8	5.8
胃切除術（幽門側）	39,957	66.7	33.3	16.3	13.5	15.8	17.8	17.6	19. 0
胃全摘術	19,035	74.0	26.0	14.7	13.5	16.9	19.4	19.2	16.3
結腸右半切除術	21,814	50.6	49.4	13.0	10.0	13.4	17.6	18.9	27.1
低位前方切除術	21,096	64.2	35.8	23.8	16.5	17.4	16.9	13.5	11.8
肝切除術（外側区域以外の区域）	7,937	69.4	30.6	19.4	14.2	18.0	20.3	18.2	9.9
膵頭十二指腸切除術	10,068	61.4	38.6	15.2	13.8	18.4	22.4	18.7	11.6
急性汎発性腹膜炎手術	10,447	60.1	39.9	29.1	10.3	11.5	11.8	13.1	24.1

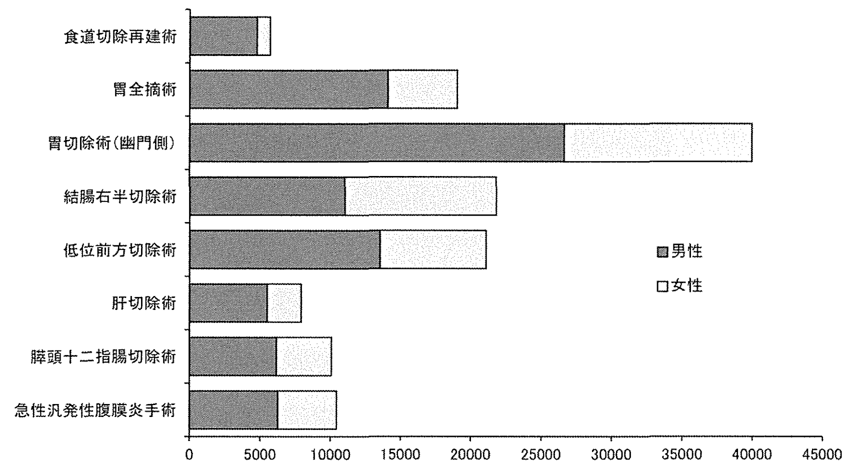

図6　主たる8術式の手術件数と性別（2013年）

腹膜炎手術では80歳以上の比率が高く，結腸右半切除術では4分の1以上が80歳以上であった（表13，図6）．

手術の行われた施設区分に関しては，おおむね7割以上が認定施設で行われ，特に食道切除再建術（92.9%），肝切除術（外側区域以外の区域）（88.1%）では認定施設で行われた手術の比率が高かった．麻酔科医関与の比率は全ての術式で90%以上であった．食道切除再建術，肝切除術（外側区域以外の区域），膵頭十二指腸切除術は90%前後が専門医の関与のもとに行われていたが，結腸右半切除術，急性汎発性腹膜炎手術の専門医関与の比率はそれぞれ69.7%，62.4%であった（表14，図7，8）．

主たる8術式の死亡率を表15に示す．急性汎発性腹膜炎手術以外では，術後30日死亡率は0.4から1.6%，手術関連死亡率は0.8から3.7%であった．急性汎発性腹膜炎手術の術後30日死亡率，手術関連死亡率はそれぞれ8.2%，13.5%であった（表15，図9）．

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表14　主たる8術式における施設区分と麻酔科医，専門医の関与（2013年）

術式	施設区分の比率（%）			麻酔科医関与の比率（%）	専門医関与の比率（%）	術者	
	認定施設	関連施設	その他			専門医（%）	非専門医（%）
食道切除再建術	92.9	5.9	1.2	98.0	90.8	66.6	33.4
胃切除術（幽門側）	76.6	19.2	4.1	93.6	76.1	40.6	59.4
胃全摘術	77.2	18.9	3.9	94.2	75.0	39.5	60.5
結腸右半切除術	72.1	22.3	5.6	92.9	69.7	32.6	67.4
低位前方切除術	76.3	19.5	4.2	93.7	75.5	44.3	55.7
肝切除術（外側区域以外の区域）	88.1	9.7	2.2	96.9	91.0	65.2	34.8
膵頭十二指腸切除術	85.9	11.7	2.4	96.0	87.9	60.5	39.5
急性汎発性腹膜炎手術	77.7	18.1	4.2	91.2	62.4	23.9	76.1

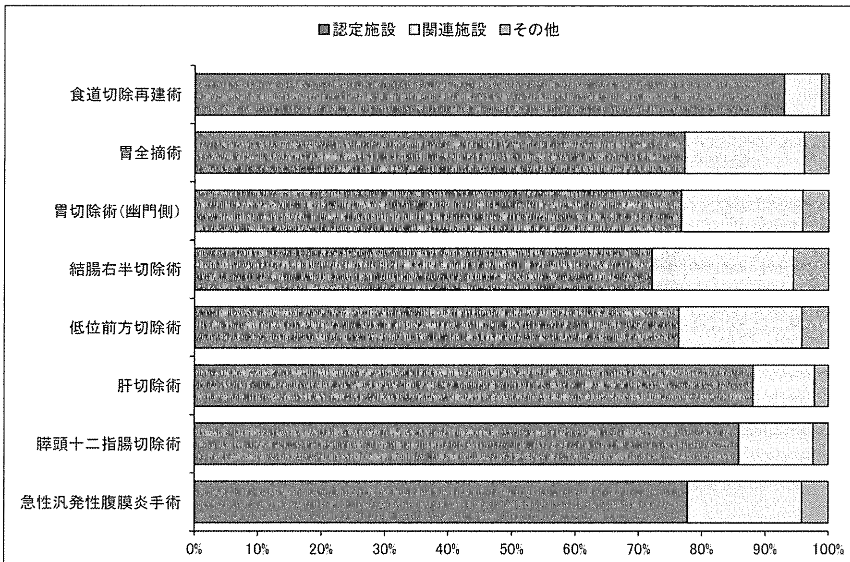

図7　主たる8術式における施設区分（2013年）

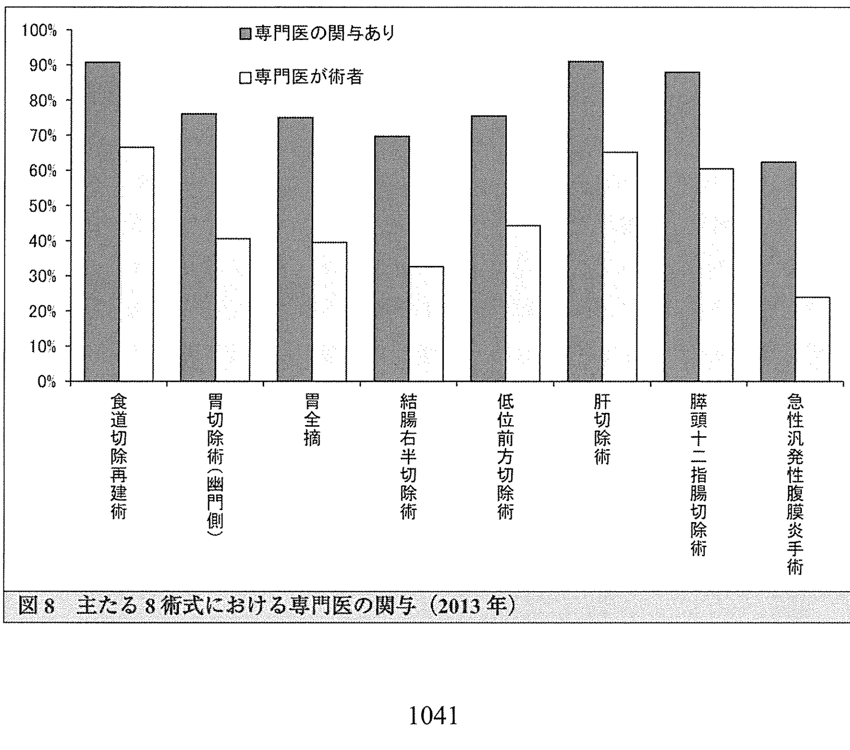

図8　主たる8術式における専門医の関与（2013年）

表 15　主たる 8 術式の手術件数と死亡率（2013 年）

術式	手術件数	術後 30 日死亡数/率（%）	手術関連死亡数/率（%）
食道切除再建術	5,694	67/1.2%	161/2.8%
胃切除術（幽門側）	39,957	239/0.6%	542/1.4%
胃全摘術	19,035	169/0.9%	428/2.2%
結腸右半切除術	21,814	280/1.3%	538/2.5%
低位前方切除術	21,096	80/0.4%	175/0.8%
肝切除術（外側区域以外の区域）	7,937	130/1.6%	290/3.7%
膵頭十二指腸切除術	10,068	142/1.4%	307/3.0%
急性汎発性腹膜炎手術	10,447	861/8.2%	1,408/13.5%

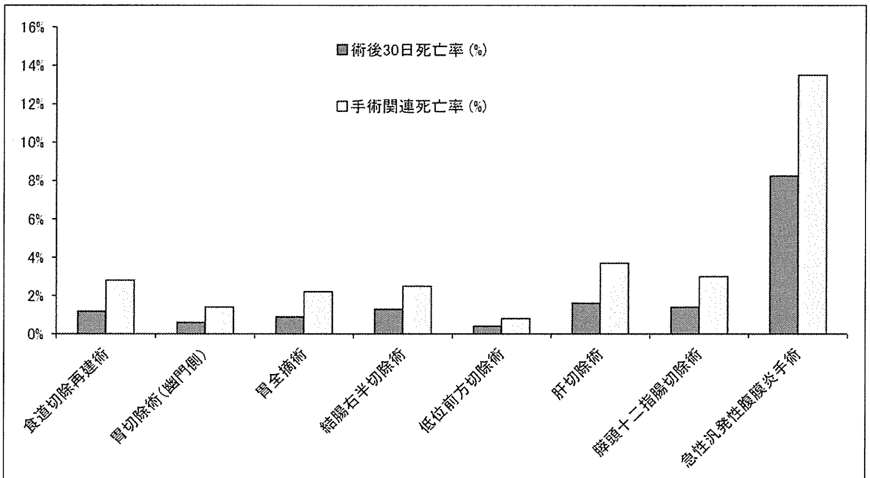

図 9　主たる 8 術式の死亡率（2013 年）

8. 利益相反

本事業に関連して，開示すべき利益相反はありません．

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SPECIAL REPORT

Annual Report of National Clinical Database in Gastroenterological Surgery 2014

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Key Words: operative mortality, complications, risk calculator

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A Risk Model for Esophagectomy Using Data of 5354 Patients Included in a Japanese Nationwide Web-Based Database

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Objective: This study aimed to create a risk model of mortality associated with esophagectomy using a Japanese nationwide database.

Methods: A total of 5354 patients who underwent esophagectomy in 713 hospitals in 2011 were evaluated. Variables and definitions were virtually identical to those adopted by the American College of Surgeons National Surgical Quality Improvement Program.

Results: The mean patient age was 65.9 years, and 84.3% patients were male. The overall morbidity rate was 41.9%. Thirty-day and operative mortality rates after esophagectomy were 1.2% and 3.4%, respectively. Overall morbidity was significantly higher in the minimally invasive esophagectomy group than in the open esophagectomy group (44.3% vs 40.8%, $P = 0.016$). The odds ratios for 30-day mortality in patients who required preoperative assistance in activities of daily living (ADL), those with a history of smoking within 1 year before surgery, and those with weight loss more than 10% within 6 months before surgery were 4.2, 2.6, and 2.4, respectively. The odds ratios for operative mortality in patients who required preoperative assistance in ADL, those with metastasis/relapse, male patients, and those with chronic obstructive pulmonary disease were 4.7, 4.5, 2.3, and 2.1, respectively.

Conclusions: This study was the first, as per our knowledge, to perform risk stratification for esophagectomy using a Japanese nationwide database. The 30-day and operative mortality rates were relatively lower than those in previous reports. The risk models developed in this study may contribute toward improvements in quality control of procedures and creation of a novel scoring system.

Keywords: 30-day mortality, esophageal cancer, esophagectomy, minimally invasive esophagectomy, operative mortality, thoracoscopic surgery

(*Ann Surg* 2014;260:259–266)

Esophageal cancer is the sixth leading cause of cancer-related mortality worldwide because of the high malignant potential and poor prognosis.[1] The postoperative 5-year survival rate in patients with American Joint Committee on Cancer stage I esophageal cancer is approximately 90%, and it decreases to 45% in patients with stage II disease, 20% in those with stage III disease, and 10% in those with stage IV disease.[2]

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Although the efficacy of chemoradiotherapy for esophageal cancer has been reported,[3–5] esophagectomy remains the mainstay of potential curative treatment for esophageal cancer. The recent improvement in long-term survival after esophagectomy can be attributed to advancements in surgical techniques for extended lymph node dissection and perioperative management.[6] However, esophagectomy is a highly invasive procedure with several serious postoperative complications, including pneumonia, anastomotic leaks, and sepsis, which may result in multiorgan failure.[7,8] A significant increase in morbidity and mortality after invasive procedures has been reported.[9–11]

Although several factors have been identified as predictors of morbidity and mortality after esophagectomy,[12–14] few have employed a large patient cohort to describe a risk model of mortality associated with esophagectomy.

Patient registration for the National Clinical Database (NCD) commenced in January 2011. It is a nationwide project that is linked to the surgical board certification system in Japan. In this study, we focused on the gastrointestinal surgery division of the NCD, which uses patient variables and definitions that are almost identical to those used by the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP).[15] Using this database, we developed a risk model of mortality associated with esophagectomy in Japan and focused on the comparison of minimally invasive esophagectomy (MIE) with open esophagectomy (OE).

PATIENTS AND METHODS

Data Collection

The NCD is a nationwide project in cooperation with the board certification system for surgery in Japan, and it collected data for more than 1,200,000 surgical cases from more than 3500 hospitals in 2011. The NCD, a Web-based data management system, continuously involves individuals who approve data, those in charge of annual case reporting from various departments, and data entry personnel, thereby assuring data traceability. Furthermore, it consecutively validates data consistency through inspections of randomly chosen institutions. Patients who refused publication of their treatment information were excluded from this study. Records with missing data or status at 30 days after surgery were also excluded. Essentially, only patients with complete data were registered in the NCD. All patients who underwent esophagectomy and were registered in the NCD were included in this study. Therefore, we have no detailed data on patients excluded because of missing data or insufficient follow-up. According to the inclusion criteria, only patients who underwent partial or total esophagectomy with reconstruction using any other organs such as the stomach, jejunum, or colon were included in this study. Therefore, 5354 patients who underwent esophagectomy in 713 hospitals from January 1, 2011, to December 31, 2011, were eligible for inclusion.

The NCD program focused on 30-day outcomes (whether or not a patient was discharged after initial admission) via direct ascertainment of the 30-day time point. Outcomes of esophagectomy include rigorously defined morbidities (ie, wound, respiratory, urinary tract, central nervous system, cardiac, and others) and mortality. The gastroenterological surgery section registers all surgical cases in the department and requires detailed input for the following items: esophagectomy, partial/total gastrectomy, right hemicolectomy, low anterior resection, hepatectomy, pancreatoduodenectomy, surgery for acute generalized peritonitis, and those cases that represent surgical procedures in each specialty. All variables, definitions, and inclusion criteria for the NCD were accessible online by the participating institutions (http://www.ncd.or.jp/), and the NCD supports an E-learning system so that participants can enter consistent data. In this study, preoperative patient variables such as clinical factors and laboratory data were almost identical to those used by the ACS NSQIP.[15] In particular, the NCD variables that were clinically suitable for esophagectomy and avoided multicollinearity for statistical analysis were chosen to create risk models of mortality following esophagectomy. The definitions of patient variables were also almost identical to those used by the ACS NSQIP.[15] Notably, the Web site is monitored and posts replies to all inquiries regarding data entry (approximately 80,000 inquiries in 2011), and it regularly posts some information under the Frequently Asked Questions tab.

Before esophagectomy, patients were generally assessed via esophagography, esophagoscopy, computed tomography, ultrasonography, endoscopic ultrasonography, and positron emission tomography in each institution. Clinical staging was performed preoperatively according to the TNM classification as proposed by the Union for International Cancer Control. Furthermore, patients' tolerance to the esophagectomy was routinely evaluated by the cardiac stress tests with electrocardiogram or echocardiogram, pulmonary function tests, blood gas analysis, and preoperative laboratory tests to assess general conditions including liver and renal functions, nutritional status, and comorbidities.

TABLE 1. Patient Clinical Parameters and Laboratory Data

	Total (n = 5354)
Age, median (25th–75th percentile), yrs	67.0 (61–72)
Sex	
Male	4511 (84.3%)
Female	843 (15.7%)
BMI, median (25th–75th percentile), kg/m^2	21.1 (18.8–23.1)
Length of hospital stay, median (25th–75th percentile), d	32.0 (23–49)
Length of ICU stay, median (25th–75th percentile), d	3.0 (2–5)
Preoperative blood tests, median (25th–75th percentile)	
WBC/mL	5600 (4430–6990)
Hemoglobin, g/dL	12.6 (11.2–13.9)
Platelet (×10,000/mL)	22.5 (18.3–27.9)
Albumin, g/dL	4.0 (3.7–4.3)
Total bilirubin, mg/dL	0.6 (0.4–0.8)
AST, U/L	20 (17–25)
ALT, U/L	16 (12–23)
ALP, U/L	221 (181–270)
Creatinine, mg/dL	0.8 (0.68–0.92)
Blood urea nitrogen, mg/dL	15 (12–19)
Sodium, mEq/L	140 (139–142)
CRP, mg/dL	0.14 (0.06–0.48)
PT-INR	1.0 (0.94–1.05)
APTT, sec	29.7 (26.6–31.8)

ALP, alkaline phosphatase; ALT, alanine aminotransferase; APTT, activated partial thromboplastin time; AST, aspartate aminotransferase; BMI, body mass index; CRP, C-reactive protein; ICU, intensive care unit; PT-INR, prothrombin time-international normalized ratio; WBC, white blood cells.

Endpoints

The primary outcome measures of this study were 30-day and operative mortalities. Operative mortality included all patients who had died within the index hospitalization period, regardless of the length of hospital stay (up to 90 days), any patient who had died after hospital discharge (up to 30 days after surgery), as well as all 30-day mortalities.

Statistical Analysis

Univariate analysis was performed using the Fisher exact test, unpaired Student *t* test, and the Mann-Whitney *U* test. To develop the risk model, data were randomly assigned to 2 subsets that were split 80/20 for model development and validation testing, respectively. The development data set included 4261 records and the validation data set included 1093 records. The 2 sets of logistic models (30-day and operative mortality) were constructed for the development data set using a stepwise selection of predictors with a *P* value of 0.05 for inclusion. A goodness-of-fit test was performed to assess the ability of the model to discriminate between survivors and deceased patients.

RESULTS

Risk Profile for the Study Population

The average age of the NCD esophagectomy patient population ($n = 5354$) was 65.9 years, and 4511 patients (84.3%) were males (Tables 1 and 2). Of the 5354 patients, only 0.8% required emergency esophagectomy. Preoperative risk and laboratory profiles for the study population are shown in Tables 1 and 2. Assistance in activities of daily living (ADL) before surgery was required in 2.0% patients, and weight loss of more than 10% during 6 months before surgery was observed in 9.2% patients. An American Society of Anesthesiologist (ASA) physical status of grade 3 or higher was observed in 7.3% patients. Histories of smoking within 1 year before surgery, preoperative habitual alcohol use, respiratory distress within 1 month before surgery, and preoperative chronic obstructive pulmonary disease (COPD) were recorded for 41.7%, 58.2%, 2.2%, and 6.1% patients, respectively. Other preoperative comorbidities included hypertension (30.5%), diabetes mellitus (12.7%), cerebrovascular disease (2.9%), and disseminated cancer (1.4%).

In the NCD, 5159 patients (96.4%) were diagnosed with esophageal cancer, 89 (1.7%) with gastric cancer involving the distal esophagus, and 21 (0.4%) with other malignancies such as head and neck cancer involving the proximal esophagus. Eighteen patients (0.3%) were diagnosed with benign tumors or gastrointestinal stromal tumors and 78 (1.3%) with benign diseases such as achalasia and corrosive esophageal injury.

Morbidity and Outcomes After Esophagectomy

The mean operative time and blood loss in the 5354 patients in the NCD esophagectomy population were 473 ± 160 minutes and 568 ± 570 mL (mean ± SD), respectively. Although we could not obtain the percentage of patients who underwent transhiatal or transthoracic approaches accurately in this study, only 232 (4.3%) of the 5354 patients underwent laparotomy (using the transhiatal approach) without thoracotomy. A total of 1751 (32.7%) patients underwent total (thoracoscopic and laparoscopic approaches) or hybrid (thoracoscopic or laparoscopic approach) MIE in the current study. Of these patients, 1436 (82.0%) underwent surgery using the thoracoscopic approach.

The overall morbidity rate in the NCD esophagectomy population was 41.9% (2244/5354). Surgical complications included surgical site infection (14.8%), anastomotic leakage (13.3%), and wound dehiscence (2.2%). Nonsurgical complications included incidences of pneumonia (15.4%), renal failure (2.4%), central nervous

TABLE 2. Preoperative Variables and Mortality

	Entire Study Population (n = 5354)		30-d Mortality (n = 63)			Operative Mortality (n = 181)		
Variables	**n**	**%**	**n**	**%**	***P***	**n**	**%**	***P***
Male	4511	84.3	57	1.3	0.222	164	3.6	0.016
Emergency operation	43	0.8	3	7.0	0.014	6	14	0.003
ADL, any assistance	105	2.0	6	5.7	0.001	21	20.0	<0.001
Weight loss, >10%	494	9.2	15	3.0	<0.001	40	8.1	<0.001
Smoking within 1 year	2230	41.7	36	1.6	0.014	80	3.6	0.491
Habitual alcohol use	3118	58.2	40	1.3	0.442	108	3.5	0.702
Respiratory distress	118	2.2	7	5.9	<0.001	21	17.8	<0.001
COPD	328	6.1	7	2.1	0.107	24	7.3	<0.001
Pneumonia	64	1.2	3	4.7	0.039	9	14.1	<0.001
Hypertension	1633	30.5	25	1.5	0.129	62	3.8	0.286
Congestive heart failure	15	0.3	2	13.3	0.013	4	26.7	0.001
Myocardial infarction	9	0.2	0	0.0	1.00	0	0.0	1.00
Angina	44	0.8	1	2.3	0.407	3	6.8	0.185
Preoperative dialysis	13	0.2	1	7.7	0.143	2	15.4	0.069
Diabetes mellitus	681	12.7	10	1.5	0.445	31	4.6	0.087
Cerebrovascular disease	157	2.9	5	3.2	0.037	13	8.3	0.002
ASA physical status								
Grade 3–5	390	7.3	12	3.1	0.002	27	6.9	<0.001
Grade 4–5	8	0.1	1	12.9	0.09	3	37.5	0.002
Grade 5	2	0.04	1	50.0	0.023	2	100	0.001
Preoperative chemotherapy	1005	18.8	9	0.9	0.420	29	2.9	0.384
Preoperative radiotherapy	263	4.9	2	0.8	0.769	7	2.7	0.603
Disseminated cancer	76	1.4	3	3.9	0.060	5	6.6	0.113

system events (1.7%), cardiac events (1.2%), and septic shock (1.8%; Table 3). The reoperation rate after esophagectomy was 8.8%. In the NCD study population, the 30-day and operative mortality rates after esophagectomy were 1.2% (63/5354) and 3.4% (181/5354), respectively. Most postoperative complications were implicated in the increased 30-day and operative mortality rates (Table 3).

Comparison of OE and MIE

We compared MIE (n = 1751) with OE (n = 3603) outcomes using the NCD (Tables 4 and 5). The preoperative ASA physical status was better, rate of preoperative chemotherapy was higher, and rate of preoperative radiotherapy was lower in the MIE group than in the OE group. The operative time was significantly longer in the MIE group than in the OE group ($P < 0.001$), whereas blood loss was markedly lesser in the MIE group than in the OE group ($P < 0.001$). Notably, overall morbidity was significantly higher in the MIE group than in the OE group (44.3% vs 40.8%, $P = 0.016$). In particular, the incidence of anastomotic leakage was significantly higher in the MIE group than in the OE group (14.9% vs 12.5%, $P = 0.016$). Moreover, the reoperation rate within 30 days was significantly higher in the MIE group than in the OE group (8.0% vs 5.6%, $P = 0.001$). However, there were no marked differences in 30-day or operative mortality rates between the OE and MIE groups.

Model Results

Univariate analysis revealed that some preoperative risk factors were significantly increased in the 30-day and operative mortality groups, including preoperative requirement of assistance in ADL (any assistance); weight loss of more than 10% within 6 months before surgery; history of smoking within 1 year before surgery; history of respiratory distress within 1 month before surgery; history of COPD, congestive heart failure, or cerebrovascular disease before surgery; and ASA physical status classification (Table 2). Preoperative chemotherapy and radiotherapy were not correlated with increased mortality.

Risk models of 30-day and operative mortality were developed. The final logistic models with odds ratio (OR) and 95% confidence intervals (CIs) are presented in Tables 6 and 7. Preoperative assistance in ADL was the most significant factor in both models (30-day mortality: OR = 4.203; 95% CI: 1.649–10.715; operative mortality: OR = 4.707; 95% CI: 2.545–8.707). In addition, the following overlapping variables between the 2 models were observed: weight loss of more than 10% within 6 months before surgery (30-day mortality: OR = 2.427; 95% CI: 1.228–4.799; operative mortality: OR = 1.983; 95% CI: 1.267–3.104) and age group (30-day mortality: OR = 1.506; 95% CI: 1.228–1.847; operative mortality: OR = 1.355; 95% CI: 1.202–1.528).

A history of smoking within 1 year before surgery (OR = 2.578; 95% CI: 1.404–4.733) was an independent variable in the 30-day mortality group (Table 6). Male sex (OR = 2.263; 95% CI: 1.236–4.144), history of COPD before surgery (OR = 2.100; 95% CI: 1.242–3.550), and presence of metastatic/relapsed cancer (OR = 4.459; 95% CI: 1.827–10.882) were identified as independent variables in the operative mortality group (Table 7). In addition, there were several independent variables in the preoperative laboratory data, such as white blood cell and platelet counts; serum albumin, sodium, and blood urea nitrogen levels; and prothrombin time-international normalized ratio (PT-INR).

The scoring system for the mortality risk models according to the logistic regression equation was as follows:

$$\text{Predicted mortality} = e\left(\beta 0 + \sum \beta i X i\right)/1 + e\left(\beta 0 + \sum \beta i X i\right).$$

βi is the coefficient of the variable Xi in the logistic regression equation provided in Table 6 for 30-day mortality, and Table 7 for operative mortality. $Xi = 1$ if a categorical risk factor is present and 0 if it is absent. For age category, $Xi = 1$ if patient age is <59; 60–64 $Xi = 2$; 65–69 $Xi = 3$; 70–74 $Xi = 4$; and ≥75 $Xi = 5$.

TABLE 3. Postoperative Complications and Mortality

	n = 5354		30-d Mortality (n = 63)			Operative Mortality (n = 181)		
	n	%	n	%	*P*	n	%	*P*
Surgery								
Operating time >6 h	4184	78.1	48	1.1	0.759	139	3.3	0.648
Bleeding 1000–2000 mL	579	10.8	9	1.6	0.41	42	7.3	<0.001
Bleeding > 2000 mL	134	2.5	7	5.2	0.001	13	9.7	0.001
Transfusion any	504	9.4	39	7.7	<0.001	93	18.5	<0.001
Transfusion over 5 U	188	3.5	24	12.8	<0.001	63	33.5	<0.001
Surgical complications								
Surgical site infection								
Superficial incision	414	7.7	11	2.7	0.008	31	7.5	<0.001
Deep incision	253	4.7	12	4.7	<0.001	26	10.3	<0.001
Organ space	495	9.2	18	3.6	<0.001	57	11.5	<0.001
Anastomotic leakage	711	13.3	20	2.8	<0.001	64	9.0	<0.001
Wound dehiscence	116	2.2	7	6.0	<0.001	17	14.7	<0.001
Nonsurgical complications								
Pneumonia	822	15.4	37	4.5	<0.001	113	13.7	<0.001
Unplanned intubation	450	8.4	42	9.3	<0.001	101	22.4	<0.001
Prolonged ventilation over 48 h	610	11.4	42	6.9	<0.001	110	18.0	<0.001
Pulmonary embolism	19	0.4	1	5.3	0.202	3	15.8	0.025
Renal failure	126	2.4	27	21.4	<0.001	64	50.8	<0.001
CNS events	91	1.7	20	22.0	<0.001	35	38.5	<0.001
Cardiac events	66	1.2	31	47.0	<0.001	43	65.2	<0.001
Septic shock	99	1.8	25	25.3	<0.001	54	54.5	<0.001
Readmission within 30 d	98	1.8	0	0.0	0.631	1	1.0	0.263
Reoperation any	470	8.8	15	3.2	<0.001	47	10.0	<0.001
Reoperation within 30 d	343	6.4	12	2.5	0.001	39	11.4	<0.001

CNS indicates central nervous system.

TABLE 4. Comparison of Preoperative Variables Between OE and MIE

	Entire Study Population (n = 5354)		OE (n = 3603)		MIE (n = 1751)		
Variables	n	%	n	%	n	%	*P*
Age, mean, yrs	65.9	—	66.1	—	65.7	—	0.15
BMI, mean, kg/m^2	21.1	—	21.1	—	21.2	—	0.29
Male	4511	84.3	3064	85.0	1447	82.6	0.025
Emergency operation	43	0.8	35	0.9	8	0.5	0.050
ADL, any assistance	105	2.0	80	2.2	25	1.4	0.058
Weight loss, >10%	494	9.2	355	9.9	139	7.9	0.023
Smoking within a year	2230	41.7	1487	41.3	743	42.4	0.425
Habitual alcohol use	3118	58.2	2067	57.4	1051	60.0	0.067
Respiratory distress	118	2.2	93	2.6	25	1.4	0.007
COPD	328	6.1	205	5.7	123	7.0	0.060
Pneumonia	64	1.2	45	1.2	19	1.1	0.69
Hypertension	1633	30.5	1098	30.5	535	30.6	0.95
Congestive heart failure	15	0.3	11	0.3	4	0.2	0.79
Myocardial infarction	9	0.2	6	0.2	3	0.2	1.00
Angina	44	0.8	29	0.8	15	0.9	0.87
Preoperative dialysis	13	0.2	10	0.3	3	0.2	0.57
Diabetes mellitus	681	12.7	477	13.2	204	11.7	0.11
Cerebrovascular disease	157	2.9	107	3.0	50	2.9	0.86
ASA physical status							
Grade 3–5	390	7.3	297	8.2	93	5.3	<0.001
Grade 4–5	8	0.1	7	0.2	1	0.1	0.29
Grade 5	2	0.04	2	0.1	0	0.0	1.00
Preoperative chemotherapy	1005	18.8	646	17.9	359	20.5	0.025
Preoperative radiotherapy	263	4.9	201	5.6	62	3.5	0.001
Disseminated cancer	76	1.4	62	1.7	14	0.8	0.007

TABLE 5. Comparison of Postoperative Complications and Mortality Between OE and MIE

	(n = 5354)		OE (n = 3603)		MIE (n = 1751)		
	n	%	n	%	n	%	P
Surgery							
Operating time, mean, min	473	—	450	—	523	—	<0.001
Bleeding, mean, mL	568	—	618	—	466	—	<0.001
Operating time > 6 h	4184	78.1	2640	73.3	1544	88.2	<0.001
Bleeding 1000–2000 mL	579	10.8	455	12.6	124	7.1	<0.001
Bleeding > 2000 mL	134	2.5	100	2.8	34	1.9	0.076
Transfusion any	504	9.4	364	10.1	140	8.0	0.014
Transfusion > 5 U	188	3.5	134	3.7	54	3.1	0.27
Overall morbidity	2244	41.9	1469	40.8	775	44.3	0.016
30-d mortality	63	1.2	46	1.3	17	1.0	0.42
Operative mortality	181	3.4	129	3.6	52	3.0	0.26
Surgical complications							
Surgical site infection							
Superficial incision	414	7.7	277	7.7	137	7.8	0.87
Deep incision	253	4.7	174	4.8	79	4.5	0.63
Organ space	495	9.2	323	9.0	172	9.8	0.32
Anastomotic leakage	711	13.3	450	12.5	261	14.9	0.016
Wound dehiscence	116	2.2	80	2.2	36	2.1	0.76
Nonsurgical complications							
Pneumonia	822	15.4	560	15.5	262	15.0	0.60
Unplanned intubation	450	8.4	305	8.5	145	8.3	0.83
Prolonged ventilation over 48 h	610	11.4	426	11.8	184	10.5	0.17
Pulmonary embolism	19	0.4	11	0.3	8	0.5	0.46
Renal failure	126	2.4	93	2.6	33	1.9	0.12
CNS events	91	1.7	65	1.8	26	1.5	0.43
Cardiac events	66	1.2	48	1.3	18	1.0	0.43
Septic shock	99	1.8	72	2.0	27	1.5	0.28
Readmission within 30 d	98	1.8	70	1.9	28	1.6	0.45
Reoperation any	470	8.8	299	8.3	171	9.8	0.080
Reoperation within 30 d	343	6.4	203	5.6	140	8.0	0.001

CNS indicates central nervous system.

TABLE 6. Risk Model for 30-Day Mortality

Variables	β Coefficient	OR	95% CI		P
Age category	0.409	1.506	1.228	1.847	<0.001
Smoking within 1 yr	0.947	2.578	1.404	4.733	0.002
ADL (any assistance)	1.436	4.203	1.649	10.715	0.003
Weight loss > 10%	0.887	2.427	1.228	4.799	0.011
Platelet > 40 (×10,000/mL)	0.919	2.507	1.128	5.570	0.024
Sodium level < 135 mEq/L	1.278	3.591	1.699	7.591	0.001
PT-INR > 1.1	0.702	2.019	1.044	3.903	0.037
WBC < 4000/mL	1.018	2.767	1.439	5.320	0.002
WBC > 12000/mL	1.295	3.650	1.180	11.288	0.025
Intercept (β_0)	−7.165				<0.001

Age category (<59, 60–64, 65–69, 70–74, and ≥75 years).

Model Performance

To evaluate model performance, both the C-index (measure of model discrimination), which was the area under the receiver operating characteristics (ROC) curve, and the model calibration across risk groups were evaluated. The C-index of 30-day and operative mortality was 0.791 (95% CI: 0.725–0.858; $P < 0.001$) and 0.776 (95% CI: 0.737–0.814; $P < 0.001$), respectively, in the development data set and 0.767 (95% CI: 0.654–0.880; $P = 0.001$) and 0.742 (95% CI: 0.666–0.819; $P < 0.001$), respectively, in the validation data set. The ROC curves of model performance in the validation data set are shown in Figure 1 (Supplemental Digital Content, available at http://links.lww.com/SLA/A543).

To clarify the influence of the choice of OE or MIE on the risk models established in this study, we applied the risk models to the OE and MIE groups. The C-indices of 30-day and operative mortality were 0.770 (95% CI: 0.697–0.844; $P < 0.001$) and 0.778 (95% CI: 0.736–0.820; $P < 0.001$), respectively, in the OE group (n = 3603) and 0.824 (95% CI: 0.742–0.906; $P = 0.001$) and 0.746 (95% CI: 0.689–0.804; $P < 0.001$), respectively, in the MIE group (n = 1751) (Figures 2 and 3; Supplemental Digital Content, available at http://links.lww.com/SLA/A543). Moreover, the calibration of the models demonstrated a favorable correlation between the predicted mortality rate and the matched observed mortality rate among the patient risk subgroups (data not shown).

TABLE 7. Risk Model for Operative Mortality

Variables	β Coefficient	OR	95% CI		P
Age category	0.304	1.355	1.202	1.528	<0.001
Sex (male)	0.817	2.263	1.236	4.144	0.008
ADL (any assistance)	1.549	4.707	2.545	8.707	<0.001
COPD	0.742	2.100	1.242	3.550	0.006
Weight loss > 10%	0.685	1.983	1.267	3.104	0.003
Cancer metastasis/relapse	1.495	4.459	1.827	10.882	0.001
Platelet < 12 (×10,000/mL)	0.684	1.981	1.014	3.870	0.045
Albumin < 3.5 g/dL	0.800	2.225	1.500	3.299	<0.001
Blood urea nitrogen < 8 mg/dL	0.938	2.555	1.251	5.218	0.010
Sodium < 138 mEq/L	0.726	2.068	1.404	3.044	<0.001
PT-INR > 1.25	1.098	2.999	1.569	5.734	0.001
WBC < 4500 /mL	0.584	1.794	1.233	2.611	0.002
Intercept (β_0)	− 6.014				<0.001

Age category (<59, 60–64, 65–69, 70–74, and ≥75 years).

DISCUSSION

In this study, a total of 5354 patients who underwent esophagectomy in 713 institutes throughout Japan were analyzed using the NCD study population data. Although perioperative management has gradually improved, the morbidity and mortality rates after esophagectomy are the highest among all types of solid tumor surgeries in Japan.[6,16] However, until now, there were no confirmed data regarding morbidity and mortality after esophagectomy based on a nationwide survey in Japan.

To the best of our knowledge, this is the first report that used the nationwide database in Japan to convincingly demonstrate the incidence of preoperative comorbidities and postoperative complications and rate of mortality among patients who underwent esophagectomy. Furthermore, we attempted to develop a risk model of mortality using preoperative variables of patients undergoing esophagectomy. In this study, the overall morbidity rate in the NCD esophagectomy population was 41.9%. Various postoperative complications included pneumonia (15.4%), anastomotic leakage (13.3%), and septic shock (1.8%). The 30-day mortality rate was 1.2% and the operative mortality rate was 3.4%. Most postoperative complications were implicated in the increased 30-day and operative mortality rates.

In this study, we could not calculate the percentage of patients with squamous cell carcinoma or adenocarcinoma. Furthermore, we could not determine the clinical and pathological stage of esophageal cancer because of the lack of data in the NCD. However, in our previous report, which was a comprehensive survey of esophageal cancer cases in 214 institutions in Japan (2004),[17] 92.7% patients who underwent esophagectomy were diagnosed with squamous cell carcinoma whereas 4.0% were diagnosed with adenocarcinoma. Also, in our previous report,[17] 23.3% patients who underwent esophagectomy were diagnosed with cStage I disease, 31.4% with cStage II disease, and 35.8% with cStage III disease (Union for International Cancer Control-TNM, 5th ed). After surgery, 22.6% patients who underwent esophagectomy were diagnosed with pStage I disease, 37.9% with pStage II disease, and 35.3% with pStage III disease. In general, patients with high-grade dysplasia, carcinoma in situ, and T1a (up to lamina propria) tumors are treated via endoscopic resection procedures such as endoscopic mucosal resection and/or endoscopic submucosal dissection in Japan.[18] The proportion of patients with each histological type and each clinical and pathological stage in the current study was thought to be similar to that in our previous report.[17]

Regarding postesophagectomy reconstruction, the NCD did not clarify the percentage of individual reconstruction procedures. However, in our previous report,[17] 83.5% esophagectomy patients underwent gastric pull-up reconstruction, 3.6% underwent colonic interposition, and 4.2% underwent jejunal interposition. The proportion of patients who underwent each reconstruction procedure in the current study was considered to be almost similar to that in our previous report.[17] Therefore, we have to consider the possibility that colonic or jejunal interposition may have influenced the data for postoperative complications in this study.

Similar to this study, only 6.0% patients underwent laparotomy using the transhiatal approach in our previous survey.[17] The specific characteristics of thoracic esophageal squamous cell carcinoma, which is much more common than esophageal adenocarcinoma in Japan, include multidirectional lymphatic flow from the primary lesion and widespread and random patterns of lymph node metastasis from the cervical region to the abdomen.[2,19] On the basis of these clinical observations, transthoracic extended radical esophagectomy with 3-field lymph node dissection is recognized as a standard procedure in Japan.[2,20] The transhiatal approach is not as common in Japan because most patients with esophageal squamous cell carcinoma, which primarily occurs in the middle thoracic esophagus, are increasingly treated via thoracoscopic approach as opposed to the transhiatal approach.

However, transthoracic esophagectomy with 3-field lymph node dissection is one of the most invasive gastrointestinal surgeries.[9–11] In fact, the overall morbidity rate in our study seemed relatively high, but it was virtually identical to those in reports from the United Kingdom (overall medical morbidity, 39%; reintervention rate because of surgical morbidity, 18%)[21] and the United States (overall morbidity, 50%).[22] In particular, postoperative pneumonia and anastomotic leakage were major problems that could not be ignored in this study, and most postoperative complications were related to increased mortality. However, a recent systematic review of short-term clinical outcomes after esophagectomy demonstrated that the incidence of pneumonia was reportedly 1.5% to 38.9% whereas that of anastomotic leaks was 0% to 35%.[23] Therefore, the morbidity rates for pneumonia (15.4%) and anastomotic leakage (13.3%) in this study may be within average ranges.

Our results also demonstrated that 30-day mortality was relatively lower in Japan (1.2%) than in the United Kingdom (4.3%),[21] United States (3.0%),[22] and other large national databases.[24] The systematic review also indicated that the 30-day mortality rate after esophagectomy was 0% to 11.1% whereas the operative mortality rate was 0% to 15.4%.[23] These results suggest that not only prevention of postoperative complications but also appropriate management is crucial to minimize mortality after esophagectomy.

Reportedly, MIE procedures such as thoracoscopic esophagectomy are increasingly performed worldwide.[25,26] In this study, we compared the outcomes of MIE with OE using the NCD and found that although there were no significant differences in 30-day or operative mortality rates between the OE and MIE groups, the incidence of anastomotic leakage and the rate of reoperation within 30 days because of surgical complications were significantly higher in the MIE group than in the OE group. However, the patient clinical background were markedly different between the 2 groups in the current study; therefore, in future studies, it is necessary to adjust the preoperative biases to objectively compare MIE and OE groups using other statistical methods such as propensity score matching. Nevertheless, our results were compatible with those from a previous study conducted in the United Kingdom by Mamidanna et al,[21] who reported the comparison of MIE with OE in the largest series of patients and confirmed the safety of MIE, even though MIE was associated with higher reoperation rates because of surgical complications and there were no marked benefits in operative mortality.

In this study, several patient and perioperative factors, including preoperative requirement of assistance in ADL; weight loss of more than 10% within 6 months before surgery; history of smoking within 1 year before surgery; history of respiratory distress within 1 month before surgery; history of COPD; congestive heart failure; and cerebrovascular disease before surgery; and ASA physical status were related to increased mortality as per univariate analysis. These results were relatively consistent with those of a previous analysis using the ACS NSQIP esophagectomy database.[22] It is likely that the preoperative requirement of assistance in ADL was because of various reasons such as comorbidities, advanced-stage esophageal cancer, and patient age.

The risk models developed in our study indicated that preoperative requirement of assistance in ADL, weight loss of more than 10% within 6 months before surgery, and age group were significant factors in both the 30-day and operative mortality models. History of smoking within 1 year before surgery, male sex, history of preoperative COPD, and abnormal preoperative laboratory test results were also identified as independent variables in the 30-day and operative mortality groups. Furthermore, presence of metastatic or relapsed cancer was significantly correlated with operative mortality. It is likely that preoperative poor general condition, as indicated by preoperative requirement of assistance in ADL, weight loss, and advanced age, were significantly correlated with mortality after esophagectomy. In addition, current smoking status and COPD are established strong predictors of pulmonary complications after esophagectomy.[22,27] Our results were compatible with those of previous analyses using large nationwide databases.[21,22] In contrast, presence of metastatic or relapsed esophageal cancer may be related to not only shorter cancer-specific survival but also high morbidity and mortality rates that have been reported in association with surgery for noncurative esophageal cancer.[6,28]

Several independent variables in the preoperative laboratory data, such as white blood cell and platelet counts; serum albumin, sodium, and blood urea nitrogen levels; and PT-INR have not been reported in previous risk models of mortality following esophagectomy.[14,21,22,24] However, abnormal laboratory test results are generally associated with poor overall health. A white blood cell (WBC) count of more than 12,000/mL and a platelet count of more than 400,000/mL may be linked to the possibility of preoperative infection and/or chronic inflammation. On the other hand, a WBC count of less than 4000/mL and a platelet count of less than 120,000/mL could be largely affected by preoperative chemo/radiotherapy. Hypoalbuminemia, which is a marker of malnutrition, is reportedly correlated with postoperative complications and mortality after esophagectomy.[29] Other abnormal laboratory data such as low sodium and blood urea nitrogen levels and extended PT-INR may result from various comorbidities, but severe liver dysfunction or liver cirrhosis because of excess alcohol use may be responsible for the abnormal laboratory test results in patients with esophageal squamous cell carcinoma.[1] Reportedly, esophagectomy in patients with cirrhosis carries a high risk of mortality and morbidity.[30] The preoperative abnormal laboratory data identified in our study can serve as novel markers for esophagectomy.

The C-indices of the 30-day and operative mortality models in the validation data set were 0.767 and 0.742, respectively. These results suggest that our risk models may be reliable and feasible in clinical practice. Although the usefulness of several scoring systems such as the Physiological and Operative Severity Score for enumeration of Mortality and Morbidity (POSSUM) in predicting the risk of esophagectomy has been reported,[31,32] these scoring systems seem to be unsuitable for prospective esophagectomy patients because the POSSUM model frequently overpredicts mortality after esophagectomy.[31,32] Therefore, we developed a novel scoring system suitable for patients with esophagectomy through these risk models, which will be evaluated in future studies.

Limitations

The use of the national database, derived from all types of patients and hospitals, would be expected to contribute to improvements in quality control of surgical procedures. However, the outcomes obtained in this study were influenced by hospital volume, training status and compliance, surgical specialization, resource utilization, and procedure-specific variables, which may change in the future.[33] However, variables pertaining to the risk of mortality in this study should be evaluated in a future study using these basic risk models. The NCD did not include information regarding clinical staging of esophageal cancer and preoperative clearance based on several clinical evaluations or the exclusion criteria of each institution. Furthermore, we could not obtain information regarding patients who avoided esophagectomy based on preoperative evaluations, and the NCD did not contain information regarding patients with prior operative histories.

We recognize that 2-field lymphadenectomy using the Ivor Lewis procedure or transhiatal esophagectomy is more commonly performed for esophageal adenocarcinoma in Western countries. Because differences in pathology may result in differences in surgical procedures, it remains unclear whether the mortality risk models developed in this study are applicable to assess patients in western countries.

Our results demonstrated favorable C-indices for 30-day and operative mortalities in the OE and MIE groups, suggesting that our risk models may not be markedly influenced by the choice of OE or MIE. However, the safety and benefits of MIE compared with those of conventional OE should be evaluated in more depth in the next study using this nationwide database.

The NCD commenced in January 2011 and has continued until 2013. To improve the contents of the NCD, we have decided to add the information of the TNM staging to the latest NCD, and we also plan to revise the NCD to add several important data for further studies.

CONCLUSIONS

We reported the first risk stratification esophagectomy study, as per our knowledge, based on a Japanese nationwide Web-based database. The 30-day and operative mortality rates in this study population were 1.2% and 3.4%, respectively, which were very satisfactory. We also developed risk models pertaining to esophagectomy, which should contribute to improvements in procedural quality control and creation of a novel scoring system suitable for esophagectomy.

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