Effects of *post-mortem* inspection techniques change on the detection capability of low public health impact diseases of slaughtered pigs: A quasi-experimental study

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Abstract

Slaughtered animals are regularly submitted to *post-mortem* inspection to ensure that all the edible parts are fit for human consumption. According to Regulation (EU) No 219/2014, pig carcasses inspection is exclusively visual as palpation and incision could lead to cross-contamination and spread of relevant zoonotic agents. However, when compared to incision and palpation, the visual method is characterized by low sensitivity; thus, the omission of incision and palpation could lead to a reduced detection capability of organic lesions. This study aims to assess the effectiveness of exclusively visual inspection to mark pulmonary and hepatic lesions associated with low public health impact diseases in pork carcasses. A quasi-experimental- before/after research protocol has been used. All the *post-mortem* inspections have been carried out in a slaughterhouse located in the province of Teramo (IT), on 7,764 swine from 2011 to 2017. Carcasses undergone the only visual inspection have shown a statistically significant reduction (p-value <0.0001) in the diagnosis of hepatic (decrease of 59%) and pulmonary diseases (decrease of 38. 5%). To overcome the limits of the low sensitivity of the visual inspection, as well as the inter-operator diagnostic variability, the high number of carcasses examined is proposed as a factor conferring external validity to the study, which provides quantitative evidence in support of the causal association between the modified inspection technique and the reduced diagnostic capacity. A further support derives from the assessment of the prevalence of hepatic and pulmonary diseases in species for whom the inspection technique is not changed.

Introduction

Background

To ensure an effective control of the main hazards, a comprehensive safety assurance framework combines preventive measures, applied on-farm level, along with at-abattoir inspections. Meat inspection plays an integral part in the monitoring system of animal diseases; it started at the end of the XIX century, with the awareness of the role of meat in transmitting foodborne diseases (Ostertag R. von, 1905). Each slaughtered animal is subjected to an *ante-mortem* visual examination and a *post-mortem* inspection (EFSA, 2011a). However, the traditional existing practices for *post-mortem* inspection, consisting in visual inspection, incision, and palpation are unable to identify high and medium-priority zoonotic agents as established by the risk assessment method: e.g., *Salmonella* spp. (Berends *et al*., 1997), *Y. enterocolitica* (Nesbakken *et al*., 2003), *T. gondii* (Gamble *et al*., 1999) and *Trichinella* spp. (EFSA, 2005b; EFSA, 2011b), typically carried by asymptomatic animals. On the other hand, the traditional method effectively identifies organic alterations which are considered of little relevance in terms of foodborne disease transmission according to expert evaluation (Fosse *et al*., 2008a; Fosse *et al*., 2008b): Abscesses, pneumonia as well as parasitic infestations, e.g., *Ascaris suum* (EFSA, 2011a; EFSA, 2016), and *Echinococcus* spp. (Garippa *et al*., 2004; Oksanen *et al*., 2016; Otero-Abad and Torgerson, 2013).

Because of the poor diagnostic sensitivity of the traditional method, especially concerning high and medium-priority zoonotic agents, and the potential deterioration of the hygienic conditions due to incision and palpation practices (*e.g*., microbial cross contamination and spread of *Salmonella* spp. on edible parts), the European legislator recommended alternative methods for the inspection of pork meat (Regulation (EU) No 219/2014). However, the potential implications of the proposed changes still have to be considered. To this extent, the impact on human and animal health should be regularly assessed by prevalence studies (EFSA, 2011a, EFSA, 2011b) as the risk-based analysis takes advantage of reliable epidemiological data. Risks not currently regarded as priorities could be reevaluated in case of significant changes in specific geographic areas or production systems. Thus, from robust epidemiological data an effective reassessment should be periodically carried out to manage new or re-emerging pathologies (Stärk *et al*., 2014; Hill *et al*., 2013).

Objectives

The aim of the study is to assess the effects of *post-mortem* inspection techniques change. The assumption is the reduction of detection effectiveness especially for hepatic and pulmonary disease consideration of little relevance in terms of foodborne transmission as a consequence of palpation and incision omission (EFSA, 2011a). According to the current estimates of prevalence, a reduction of the detection effectiveness is accepted; however, data from epidemiological surveys could lead to a risk assessment review.

Primary objective: diagnostic effectiveness of the visual method regarding pathologies considered of little relevance in terms of foodborne transmission. Secondary objective: large scale prevalence study of hepatic and pulmonary alterations detected during the *post-mortem* examination and the potential resulting exclusion of meat consumption for hygienic and safety risk. Moreover, the *post-mortem* diagnostic agreement is assessed as well (Schleichera *et al*., 2013).

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Materials and methods

Study design

Quasi-experimental observational before/after study with non-equivalent control groups. The study design compares the capability of detecting hepatic and pulmonary alterations of pork carcasses undergone visual examination, incision, and palpation and the ones exclusively exposed to visual inspection. As it has not been possible to assess the detection changes directly on pork carcasses, due to the variation of the inspection method prescribed by law, bovine and ovine species have been introduced as control groups. The presence of control groups offers the possibility to carry out a comparison of hepatic and pulmonary disease prevalence in species for whom the inspection technique is not changed. The main drawbacks of the study are the poor sensitivity of the *post-mortem* visual inspection, used as the sole method of diagnosis for pork carcasses, and the variability of the inter-operator agreement as a consequence of the individual subjectivity. The lack of randomization could lead to measurement uncertainties, as systematic errors and confounding bias, thus possibly impairing the causality analysis. As the causality analysis is therefore limited, the selection bias has been controlled using the censor method and the measurement bias with restrictions. To monitor the assessment bias and the differential misclassification, pulmonary abnormalities have not been considered as pathological cases when consequence of errors during the slaughter process which led to the distortion of lung normal anatomy.

Setting

The study took place in a single slaughterhouse located in the province of Teramo over a period of 6 years. The study comprehended swine, bovine, and ovine animals slaughtered from 04/04/2011 to 30/04/2017. It is likely that for most diseases showing clinical signs, the prevalence is lower in the studied population if compared to the general one as animals sent to the slaughterhouse are generally those with a better state of health (EFSA, 2011a; EFSA, 2011b). Inspection, by definition, is a census; examining the whole population at slaughterhouse allows a valid assessment of disease prevalence and their detection. All the swine (*Sus scrofa domesticus*) were crossbred Large White or Landrace from small and medium farms in the province of Teramo; sheep (*Ovis aries*), both raised at national and foreign level, were either lambs (3-5 months) or adults; cattle (*Bos taurus*) were either fattened or at the end of their career. Acceptance criteria: alive animals, regularly admitted to the ordinary slaughter procedure, presenting detectable hepatic and pulmonary lesions (EFSA, 2013b; Dupuy *et al*., 2014). Exclusion criteria: swine: carcasses weight lower than 25 kg; sheep: carcasses weight lower than 12 kg; cattle: animals younger than 8 months. Additionally, all the subjects for whom no hepatic and pulmonary lesions could be detected through visual inspection, have not been included.

Data collection and management

The *post-mortem* inspection results have been recorded and collected over a period of 6 years (73 months), from 2011 to 2017. The assessment over six complete seasonal cycles is meant to control any potential variability factor. During the study, the inspection of 7,764 swine, 20,161 cattle, and 34,062 sheep has been carried out totaling 61,987 observations. Each record of any pathological finding has been drawn up and registered by an official veterinarian responsible for the final decision to authorize the human consumption of edible parts; seventeen official veterinarians took part during the observation period.

Intervention and comparison

The overall number of animals examined before and after the *post-mortem* inspection change imposed by Regulation (EU) No 219/2014 is balanced: 32,318 and 29,669 observations, respectively. Swine represented 12.5% of the overall observations, cattle 32.5%, and sheep 55%. The organic (hepatic and pulmonary) lesions identified through visual inspection are considered of little relevance in terms of foodborne disease transmission according to the risk-based analysis; however, their presence could lead to condemnation. Hepatic lesions are easily detected thanks to the anatomical conformation of the organ. As regards the pulmonary inspection, it is impaired by the limited commercial value; moreover, especially in pork carcasses, it is affected by frequent errors during the slaughter process, which lead to post-mortem morphological changes, complicating the judgment of the competent authority. As discussed, the rapid *ante-mortem* visual examination is characterized by poor diagnostic sensitivity even in case of diseases and conditions with major anatomopathological signs. On the other hand, the sensitivity of the *post-mortem* inspection is influenced by the skills, training, experience, and commitment of the official veterinarian, as well as the slaughter line layout and speed, and the number of inspectors (Hill *et al*., 2013). It also depends on the nature and degree of the organic pathological alteration as well as on the prevalence in the examined population (EFSA, 2011a; EFSA, 2011b; Stärk *et al*., 2014; Schleichera *et al*., 2013). However, in certain situations to obtain an etiological diagnosis, although not required by regulation, laboratory tests should be carried out. For the purpose of this study, only hepatic and pulmonary lesions routinely pointed out in *post-mortem* inspection (Blagojevic and Antic, 2014), and responsible for exclusion from human consumption (Regulation (CE) 854/2004, in force during the study), have been considered as cases: hepatitis, nonspecific acute perihepatitis, and hepatic changes resulting from the underlying disorders; acute nonspecific pleuropneumonia, and pulmonary changes due to the underlying disorder; lesions due to parasitic infestation (echinococcosis/hydatid disease, hepatic-pulmonary parasitosis from nematodes, distomatosis); acute and chronic degenerative processes including neoplasia. Other causes of exclusion from human consumption as fecal contamination, scalding water drawn-off, and errors during animal stuck have been considered as well.

Variables

The variables analyzed in the present study have been differentiated in exposure variables and result variables. The exposure variables concerned the *post-mortem* inspection change, from the traditional method (visual inspection, incision, and palpation) to the exclusively visual one; the time setting: before and after the changes resulting from the application of Regulation (EU) No 219/2014; the species included in the investigation: porcine (under study), bovine, and ovine species (comparison/control groups); the seventeen official veterinarians who took turns during the study. The result variables referred to: hepatic alterations, pulmonary alterations, and decisions concerning meat intended for human consumption.

Statistical analysis

The statistical analysis has been performed to assess whether the changes introduced by Regulation (EU) No 219/2014 on *post-mortem* inspection technique, starting 01 June 2014, have reduced the likelihood of detecting hepatic and pulmonary lesions in pigs. The analysis has considered all the carcasses examined from 04 April 2011 to 30 April 2017 implementing a quasi-experimental study before/after with two different non-equivalent control groups as comparison. Comparing the two observation periods (as the application of Regulation (EU) No 219/2014 was set on 01 June 2014)

it has been possible to identify differences related to the detection capability before and after the inspection technique change. The study model has used the χ^2 test for categorical (binary) exposure variables and has returned a p-value. The χ^2 statistical significance test has analyzed the prevalence of hepatic and pulmonary lesions over the two reference periods, as a consequence of the Regulation compulsory application. The presence of the two different control groups has been functional to monitor the confounding variables and to assess the real impact of changing the *post-mortem* inspection, concerning only swine, since it has not been possible to apply to the model the ex-post monitoring of the confounding variables occurred during the analysis phase (Shardell *et al*., 2007; Harris *et al*., 2006). The statistical software STATA (Stata Corporation, College Station, Texas), version 14.0, has been used for all the statistical analysis.

Results

During the first period (04/04/2011 - 31/05/2014), 3,572 swine (46%) were subjected to the traditional *post-mortem* inspection method whereas over the second period (01/06/2014 - 30/04/2017), 4,192 swine (54%) were subjected to only visual inspection. The overall cattle and sheep, 20,161 and 34,062 respectively, have undergone the complete *post-mortem* inspection throughout the study. The occurrence of hepatic and pulmonary lesions is shown in Tables 1 and 2. Regarding swine, the prevalence observed over the two different periods, shown in Table 3. highlights a statistically significant reduction of the outcome levels (p-value <0.0001). The hepatic and pulmonary lesions decreased by 59% and 38.5% respectively (Figure 1). The occurrence of hepatic and pulmonary cases over years is shown in Table 2. As to swine, there was a progressive increase from 2011 to 2013; this trend stopped in 2014 and was reversed from 2015 to 2017.

Considering cattle, no significant variations concerned either hepatic (p-value 0.131) or pulmonary lesions (p-value 0.550) (Table 3). However, as regards sheep there was a significant reduction (p-value <0.0001) (Table 3) in both hepatic (-51%) and pulmonary lesions (-48%) (Figure 1). In cattle, the occurrence of organic lesions did not register any unexpected peak over the observed period with a range of 3.5-5.6%. For sheep a clear reduction of the hepatic lesions was observed from 2011 to 2017 with a negative peak in 2014, along with pulmonary alterations with two significant drops in 2013 and 2016 (Table 2).

During the second observation period, the presence of both hepatic and pulmonary lesions (Figure 1) significantly decreased both for pork carcasses that were subjected to visual inspection and sheep carcasses for whom the classical *post-mortem* examination has been performed.

Table 4 shows the cases of meat declared unfit for human consumption: it includes meat from animals whose organs were affected by diseases (as listed in Regulation (CE) 854/2004, in force during the study) or as a consequence of the failure of any hygienic criteria throughout the slaughtering process. The cases of exclusion of lung significantly increased for swine mainly because of scalding water drawn-off (p-value <0.0001); for cattle no significant differences have been underlined (p-value 0.064); while, for sheep a

Table 1. Occurrence of pathologies observed before and after the inspection technique change in pigs.

Observation period	04/04/2011 31/05/2014 *before*		01/06/2014 30/04/2017 *after*		04/04/2011 30/04/2017 *full period*	
	N.	%	N.	%	N.	%
Experimental Group Pig						
Observations	3572	46	4192	54	7764	100
Hepatic disease	566	15.85	272	6.49	838	10.79
Pulmonary disease	215	6.02	155	3.70	370	4.77
Control Group Bovine						
Observations	11717	58	8444	42	20161	100
Hepatic disease	571	4.87	373	4.42	944	4.68
Pulmonary disease	320	2.73	218	2.58	538	2.67
Control Group Sheep						
Observations	17029	50	17033	50	34062	100
Hepatic disease	7709	45.27	3814	22.39	11523	33.82
Pulmonary disease	8369	49.15	4362	25.61	12731	37.38

Table 2. Occurrence of diseases by species and year.

	Hepatic disease				Pulmonary disease		
year	Pig %	Bovine %	Sheep %	year	Pig %	Bovine %	Sheep %
2011*	13.11	4.59	55.04	2011*	4.55	2.75	64
2012	10.49	5.32	48.69	2012	7.71	3.20	52.21
2013	19.85	4.34	40.22	2013	8.31	1.85	39.18
2014	18.44	5.61	28.94	2014	8.10	3.29	32.68
2015	6.98	4.68	27.34	2015	6.15	2.64	33.85
2016	5.27	3.59	18.58	2016	0.16	2.28	18.44
2017†	1.29	3.46	9.28	2017†	0	2.27	13.48

*From 04/04/2011; †to 30/04/2017.

considerable reduction has been evidenced (p-value <0.0001). Table 5 provides the contribution to the diagnosis of the 17 official veterinarians. The proportion of cases diagnosed by each operator and the dispersion measures show wide variability (range 5-41%). The comparison between the two examined periods is equally polarized, resulting in a non-differential misclassification.

Discussion and conclusions

The findings of the study support the hypothesis that the *post-mortem* inspection change could reduce the ability to diagnose organic lesions and pathologies considered of little relevance in terms of foodborne disease transmission, since a relevant reduction in number has been associated with pork carcasses exposed only to the visual inspection. Considering cattle, no significant prevalence variation has been marked in contrast to sheep suggesting at least partly, the role of external, independent variables falling outside the *post-mortem* inspection itself. Indeed, even if both cattle

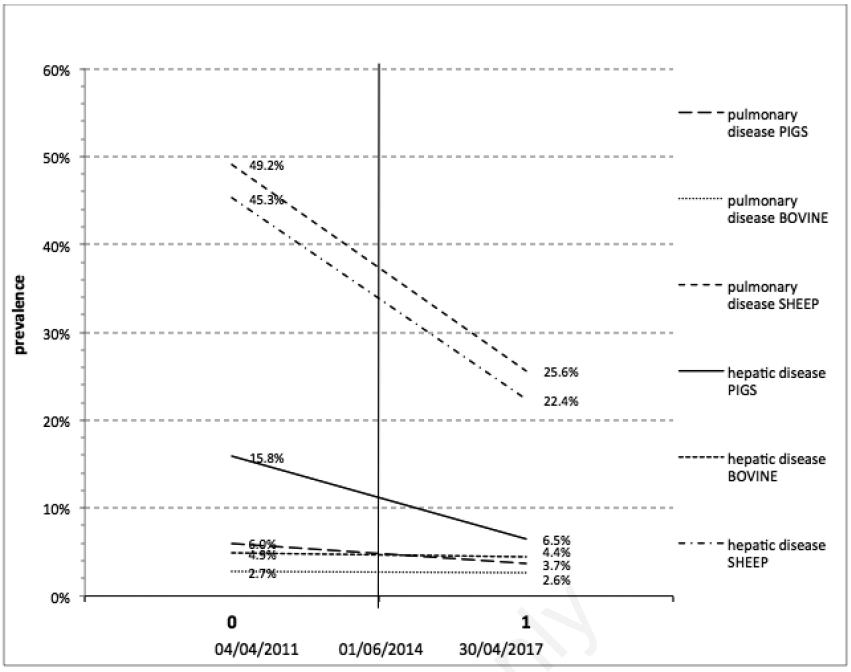

Figure 1. Comparison of hepatic and pulmonary lesions before and after the changes introduced with Regulation (EU) No 219/2014.

Table 3. Outcomes by pathology and by group.

Observation period	04/04/2011 31/05/2014 *before*		01/06/2014 30/04/2017 *after*		04/04/2011 30/04/2017 *full period*		p-value
	N.	%	N.	%	N.	%	
Experimental Group Pigs							
Hepatic disease -	3006	84.15	3920	93.51	6926	89.21	
Hepatic disease +	566	15.85	272	6.49	838	10.79	< 0.0001
Pulmonary disease -	3357	93.98	4037	96.30	7764	95.23	
Pulmonary disease +	215	6.02	155	3.70	370	4.77	< 0.0001
Control Group Bovine							
Hepatic disease -	11146	95.13	80.71	95.58	19217	95.32	
Hepatic disease +	571	4.87	373	4.42	944	4.68	0.131
Pulmonary disease -	11397	97.27	8226	97.42	19623	97.33	
Pulmonary disease +	320	2.73	218	2.58	538	2.67	0.550
Control Group Sheep							
Hepatic disease -	9320	54.73	13219	77.61	22539	66.17	
Hepatic disease +	7709	49.15	3814	22.39	11523	33.82	< 0.0001
Pulmonary disease -	8660	50.85	12671	74.39	21331	62.62	
Pulmonary disease +	8369	49.15	4362	25.61	12731	37.38	< 0.0001

3302 excluded from consumption for reasons of hygiene are considered.

Table 4. Outcomes by pathology and by group. Decisions concerning meat.

	Before		After		Full		p-value
	N.	%	N.	%	N.	%	
Pigs							
Declared fit for human consumption	952	26.65	949	22.64	1901	24.48	
Total unfit for consumption (carcass)	4	0.11	0		4	0.05	
Partial unfit for consumption (liver/lung)	2616	73.24	3243	77.36	58.59	75.46	<0.0001
Bovine							
Declared fit for human consumption	10947	93.43	7936	93.98	18883	93.66	
Total unfit for consumption (carcass)	21	0.18	23	0.17	44	0.22	
Partial unfit for consumption (liver/lung)	749	6.39	485	5.74	1234	6.12	0.064

Table 5. Centrality and dispersion index.

Veterinarians		Observations						Hepatic pathologies		Pulmonary pathologies	
N.	ID	Obs	% obs	Obs before	% before	Obs after	% after	n. diagnoses	% on obs	n. diagnoses	% on obs
1	A	13684	22.07	7391	54.01	6293	45.99	3555	25.98	3476	25.40
2	B	14924	24.07	5226	35.02	9698	64.98	3500	23.45	3622	24.27
3	C	8435	13.60	8435	100	0	0	2626	31.13	2902	34.40
4	D	7902	12.74	3920	49.61	3982	50.39	811	10.26	961	12.16
5	E	3635	5.86	1563	43.00	2072	57	362	9.96	303	8.34
6	F	3315	5.36	1112	33.54	2203	66.46	605	18.25	489	14.75
7	G	2768	4.47	1015	36.67	1753	63.33	355	12.83	414	14.96
8	H	2074	3.35	919	44.31	1155	55.69	528	25.46	559	26.95
9	I	1447	2.34	735	50.79	712	49.21	134	9.26	130	8.98
10	L	1037	1.69	936	90.26	101	9.74	354	34.14	279	26.90
11	M	785	1.27	144	18.34	641	81.66	170	21.66	180	22.93
12	N	639	1.03	330	51.64	309	48.36	189	29.58	182	28.48
13	O	579	0.93	400	69.08	179	30.92	28	4.84	26	4.49
14	P	417	0.67	17	4.08	400	95.92	26	6.24	57	13.67
15	Q	201	0.32	93	46.27	108	53.73	38	18.91	35	17.41
16	R	101	0.16	38	37.62	63	62.38	6	5.94	6	5.94
17	S	44	0.07	44	100	0	0	18	40.91	18	40.91
Total amount		61987	100	32318	52.14	29669	47.86	13305		17127	
Mean		3646	5.88	1901	50.84	1745	49.16	782	19.34	802	19.46
Median		1447	2.34	919	46.27	641	53.73	354	18.91	279	17.41
Range		44-14924	0.07-24.07	17-8435	4.08-100	0-9698	0-95.92	6-3555	4.84-40.91	6-3622	4.49-40.91
Standard deviation		4733	7.63	2673	26.25	2652	26.25	1203	10.92	1239	10.36

and sheep were expected to have prevalence patterns similar to the historical trend, the two species are marked by zootechnical and dietary differences. Both hepatic and pulmonary lesions in sheep decreased over the whole study period. The potential underlying causes are the following: improvement of sheep farms hygienic conditions, stricter respect of the biosafety standards, and refinement of the production cycle management to meet stringent market quality requirements. Nonetheless, the same causes can not be excluded for swine as well.

The cost-benefit ratio of *post-mortem* inspection, expressed per animal, is convenient as it does not impair the production speed line while guaranteeing consumer safety through the exclusion of meat unsafe or unfit for human consumption (Table 5). It is necessary to improve the communication between official veterinarians and primary production operators to report the pathologies highlighted during the *post-mortem* inspection to schedule appropriate preventive and mitigating measures and to improve the reliability of food chain information (Cecchetto and Ruffo, 2011). Besides, the constantly updating of databases could be helpful in checking the prevalence trend over time to take any action needed.

Despite the nature of the quasi-experimental studies does not allow a clear causal association between the inspection technique changes and the reduced diagnostic capacity, the high number of carcasses evaluated confers external validity to the study. The suggested hypothesis seems highly plausible as the quasi-experimental model provides quantitative evidence in support of the causal association between the modified *post-mortem* inspection technique and the reduced diagnostic capacity. As an overall evaluation, the acquired evidence should pave the way to a thorough demonstration through experimental models with major intrinsic validity.

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